

MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

Administered by



**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ABALOPARATIDE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
ABALOPARATIDE	TYMLOS	44231		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **ABALOPARATIDE (Tymlos)** requires a diagnosis of osteoporosis. In addition, the following must be met:

- The patient is 18 years of age or older
- The patient is female and postmenopausal
- The requested medication is intended for the treatment of osteoporosis
- The patient has documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) for **ALL** the following:
 - The patient has a baseline T-score less than or equal to -3 with a previous low-impact fracture
 - The patient has documented failure despite compliance for at least 2 years, intolerance or contraindication to an oral bisphosphonate
 - The patient has documented failure or intolerance to a compliant (at least 12 months) regimen of Reclast (zoledronic acid)

RENEWAL CRITERIA:

The guideline named **ABALOPARATIDE (Tymlos)** requires a diagnosis of osteoporosis. In addition, the following must be met with documentation (e.g. labs, medical records, special studies and/or physician attestation):

- Total duration of parathyroid hormone (e.g., Forteo, Tymlos) therapy has not exceeded a total of 24 months during the patient's lifetime
- The patient is responding to treatment with evidence of maintenance or improved T-Score on DEXA scan

RATIONALE

To ensure appropriate use of abaloparatide (Tymlos) is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

TYMLOS is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

TYMLOS reduced the risk of vertebral fractures and nonvertebral fractures in postmenopausal women with osteoporosis.

CONTINUED ON NEXT PAGE

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ABALOPARATIDE (MICHIGAN MEDICAID)

Limitation of Use:

Cumulative use of TYMLOS and parathyroid hormone analogs (e.g. teriparatide) for more than 2 years during a patient's lifetime is not recommended, due to unknown relevance of the rodent osteosarcoma findings to humans.

DOSAGE AND ADMINISTRATION

- The recommended dose of TYMLOS is 80 mcg subcutaneously once daily.
- Patients should receive supplemental calcium and vitamin D if dietary intake is inadequate.

For further dosing and administration instructions, please refer to the Prescribing Information for Tymlos.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy.
- No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy

REFERENCES

- Tymlos [Prescribing Information]. Waltham, MA: Radius Health Inc.; July 2018.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ACITRETIN (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
ACITRETIN	SORIATANE	07827		

INITIAL CRITERIA:

The guideline named **ACITRETIN (Soriatane)** requires a diagnosis of moderate to severe psoriasis. In addition, the following criteria must be met:

- The patient is 18 years of age or older
- The requested medication is prescribed by or in consultation with a dermatologist
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) for **BOTH** of the following:
 - The patient has had a 90-day trial of methotrexate **AND**
 - The patient has had a trial of high dose topical steroid (e.g. betamethasone augmented, clobetasol, or halobetasol)

RENEWAL CRITERIA:

The guideline named **ACITRETIN (Soriatane)** requires a diagnosis of moderate to severe psoriasis. In addition, the following criterion must be met as documented by labs, medical record, special studies and/or physician attestation:

- The patient has experienced a positive response to Soriatane therapy

RATIONALE

To ensure appropriate use of Soriatane is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

SORIATANE is indicated for the treatment of severe psoriasis in adults.

DOSAGE AND ADMINISTRATION

The recommended dose of Soriatane is as follows:

- Initiate with 25mg to 50mg orally once daily, given as a single dose with the main meal.
- Maintenance doses of 25mg to 50mg per day may be given dependent upon an individual patient's response to initial treatment.
- Individualizing the dosage is required to achieve sufficient therapeutic response while minimizing side effects, as a number of the more common side effects as dose-related.

For further dosage and administration details, please refer to the Prescribing Information for Soriatane.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Soriatane must not be used by females who are pregnant, or who intend to become pregnant during therapy or at any time for at least 3 years following discontinuation of therapy.
- Soriatane is contraindicated in patients with impaired liver or kidney function and in patients with chronic abnormally elevated blood lipid values.
- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy.
- The patient demonstrated no clinically significant improvement in condition that has occurred after initiation of drug therapy with Soriatane.

CONTINUED ON THE NEXT PAGE

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ACITRETIN (MICHIGAN MEDICAID)

SPECIAL CONSIDERATIONS

- Pregnancy Category X
- Soriatane should not be taken with methotrexate or tetracyclines
- Soriatane should not be used in patients with known alcohol abuse

REFERENCES

- Soriatane [Prescribing Information]. Research Triangle Park, NJ: Stiefel Laboratories Inc.; October 2018.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ADALIMUMAB (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
ADALIMUMAB	HUMIRA		37262 99439 97005 18924	

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **ADALIMUMAB (Humira)** requires a diagnosis of ankylosing spondylitis, hidradenitis suppurativa, plaque psoriasis, rheumatoid arthritis, psoriatic arthritis, polyarticular juvenile idiopathic arthritis, crohn's disease, ulcerative colitis, pediatric crohn's disease or non-infectious uveitis. In addition, the following criteria must also be met:

For patients with active ankylosing spondylitis (AS), approval requires:

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient has documentation (e.g. labs, medical record, chart notes, special studies and/or physician attestation) of **ALL** the following:
 - The patient has a negative TB test within the last 12 months
 - The patient must not have heart failure
 - The patient must have the presence of active disease for at least 4 weeks
 - The patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of 4 or more
 - The patient has had a previous trial and failure to at least **TWO** NSAIDs (non-steroidal anti-inflammatory drugs) totaling 90 consecutive days
 - The patient has had a previous trial and failure of steroid products, sulfasalazine **OR** methotrexate for at least 90 consecutive days in the previous 120 day period

For patients with a diagnosis of severe and refractory hidradenitis suppurativa (HS) approval requires:

- Therapy is prescribed by or given in consultation with a dermatologist
- The patient has documentation (e.g. labs, medical record, chart notes, special studies and/or physician attestation) of **ALL** the following:
 - The patient has severe and refractory hidradenitis suppurativa (i.e. Hurley Stage II or III)
 - The patient has a negative TB test within the last 12 months
 - The patient must not have heart failure
 - Patient understanding of general healthy habits and measures (e.g., education and support, avoidance of skin trauma, hygiene, dressings, smoking cessation, weight management, diet)
 - The patient has had inadequate response to intralesional corticosteroids
 - The patient has had inadequate response to procedural interventions (punch debridement) in combination with pharmacologic therapies

CONTINUED ON THE NEXT PAGE

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ADALIMUMAB (MICHIGAN MEDICAID)

- The patient has had a previous trial and failure of systemic **AND** topical antibiotic therapy that includes **BOTH** of the following:
 - 3 months of topical antibiotics
 - 3 months of doxycycline **OR** 3 months of clindamycin plus rifampin
- The patient has had a previous trial and failure of hormonal therapy (oral contraceptive containing estrogen/norgestrel or finasteride) for 6 months in combination with antibiotic therapy
- The patient has had a previous trial and failure of infliximab

For patients with moderate to severe chronic plaque psoriasis (PsO), approval requires:

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a dermatologist
- The patient has documentation (e.g. labs, medical record, chart note, special studies and/or physician attestation) of **ALL** the following:
 - The patient has a negative TB test within the last 12 months
 - The patient must not have heart failure
 - The patient has had a previous trial and failure of methotrexate for 90 consecutive days in the previous 120 day period, or contraindication to methotrexate
 - The patient has >10% BSA involvement of affected area includes palms, soles, head, neck, or genitalia
 - The patient has had a previous trial and failure or intolerance to topical agents and **ONE** additional systemic therapy (cyclosporine, or acitretin)
 - The patient has had a previous trial and failure of UVB or UVA therapy or contraindication to therapy

For patients with active rheumatoid arthritis (RA) or active psoriatic arthritis (PsA), approval requires:

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient has documentation (e.g. labs, medical record, chart notes, special studies and/or physician attestation) of **ALL** the following:
 - The patient has a negative TB test within the last 12 months
 - The patient must not have heart failure
 - The patient has had a previous trial and failure of methotrexate for at least 90 consecutive days in the previous 120 day period, or contraindication/intolerance to methotrexate
 - The patient has tried and failed at least **ONE** other non-biologic DMARD (sulfasalazine, cyclosporine, hydroxychloroquine or leflunomide) as monotherapy or in combination for at least 3 months or contraindication/intolerance

For patients with moderate to severe active polyarticular juvenile idiopathic arthritis (JIA), approval requires:

- The patient is 2 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist

CONTINUED ON THE NEXT PAGE

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ADALIMUMAB (MICHIGAN MEDICAID)

- The patient has documentation (e.g. labs, medical record, chart notes, special studies and/or physician attestation) of **ALL** the following:
 - The patient has a negative TB test within the last 12 months
 - The patient must not have heart failure
 - The patient has had a previous trial and failure of methotrexate for at least 90 consecutive days in the previous 120 day period, or contraindication/intolerance to methotrexate
 - The patient has tried and failed at least **ONE** other non-biologic DMARD (e.g. sulfasalazine, hydroxychloroquine or leflunomide) for 3 months

For patients with active crohn's disease (CD) or ulcerative colitis (UC), approval requires:

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient has documentation (e.g. labs, medical record, chart notes, special studies and/or physician attestation) of **ALL** the following:
 - The patient has a negative TB test within the last 12 months
 - The patient must not have heart failure
 - The patient has had a previous trial and failure of oral or intravenous corticosteroids for at least **ONE** month or a contraindication/intolerance to corticosteroids
 - The patient has had a previous trial and failure of **TWO** or more of the following for 90 consecutive days in the previous 120 day period, or a contraindication or intolerance to:
 - Azathioprine
 - Budesonide
 - Oral aminosalicylates (e.g., mesalamine, sulfasalazine, balsazide disodium)
 - Rectal aminosalicylates
 - Cyclosporine
 - Mercaptopurine
 - Remicade

For patients with severe crohn's disease (CD) or ulcerative colitis (UC), approval requires:

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient has documentation (e.g. labs, medical records, chart notes, special studies and/or physician attestation) of **ALL** the following:
 - The patient has a negative TB test within the last 12 months
 - The patient must not have heart failure
 - The patient must have previously responded to Humira doses every other week
 - The patient must be experiencing a flare
 - The flare must be likely to result in hospitalization

CONTINUED ON THE NEXT PAGE

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ADALIMUMAB (MICHIGAN MEDICAID)

For patients with pediatric crohn's disease (CD), approval requires:

- The pediatric patient is between 6 and 18 years of age
- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient has documentation (e.g. labs, medical record, chart notes, special studies and/or physician attestation) of **ALL** the following:
 - The patient has a negative TB test within the last 12 months
 - The patient must not have heart failure
 - The patient has had an inadequate response to **TWO** of the following:
 - Corticosteroids
 - Azathioprine
 - Methotrexate

For patients with non-infectious uveitis, approval requires:

- Therapy is prescribed by or given in consultation with an ophthalmologist or rheumatologist
- The patient has documentation (e.g. labs, medical record, chart notes, special studies and/or physician attestation) of **ALL** the following:
 - The patient has a negative TB test within the last 12 months
 - The patient must not have heart failure
 - The patient has had a trial and failure of periocular, intraocular, or systemic corticosteroids
 - The patient has had a trial and failure of immunosuppressive drugs (e.g. azathioprine, cyclosporine, mycophenolate, or methotrexate) at maximally tolerated doses
 - The patient has had a trial and failure of or intolerance to infliximab

RENEWAL CRITERIA:

The guideline named **ADALIMUMAB (Humira)** requires a diagnosis of active ankylosing spondylitis (AS), severe and refractory hidradenitis suppurativa (HS) (i.e. Hurley Stage II or III), moderate to severe chronic plaque psoriasis (PsO), active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), moderate to severely active polyarticular juvenile idiopathic arthritis (JIA), crohn's disease (CD) or ulcerative colitis (UC) , pediatric crohn's disease (CD), or non-infectious uveitis. In addition, the following criteria must be met:

- The prescriber documents the patient continues to have a beneficial response to Humira therapy
- The patient has documented yearly negative TB tests
- Only for the diagnosis of crohn's disease(CD)/ulcerative colitis (UC), approval requires the patient to have evidence of clinical remission by week 8 for continuation of Humira therapy

CONTINUED ON THE NEXT PAGE

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ADALIMUMAB (MICHIGAN MEDICAID)

RATIONALE

To ensure appropriate use of adalimumab (Humira) is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

HUMIRA is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. HUMIRA can be used alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs).

HUMIRA is indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. HUMIRA can be used alone or in combination with methotrexate.

HUMIRA is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis. HUMIRA can be used alone or in combination with non-biologic (DMARDs).

HUMIRA is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

HUMIRA is indicated for reducing signs and symptoms, inducing, and maintaining clinical remission in adults with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. HUMIRA is indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.

HUMIRA is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate.

HUMIRA is indicated for inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine, or 6-mercaptopurine (6-MP). The effectiveness of HUMIRA has not been established in patients who have lost response to or were intolerant to TNF blockers.

HUMIRA is indicated for the treatment of moderate to severe hidradenitis suppurativa.

HUMIRA is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients.

DOSAGE AND ADMINISTRATION

Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis

40 mg every other week. Some patients with RA not receiving methotrexate may benefit from increasing the frequency to 40 mg every week.

CONTINUED ON THE NEXT PAGE

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ADALIMUMAB (MICHIGAN MEDICAID)

Juvenile Idiopathic Arthritis

The recommended dose of HUMIRA for patients 2 years of age and older with polyarticular juvenile idiopathic arthritis (JIA) is based on weight as shown below:

10 kg (22 lbs.) to <15 kg (33 lbs.): 10 mg every other week

15 kg (33 lbs.) to <30 kg (66 lbs.): 20 mg every other week

≥30 kg (66 lbs.): 40 mg every other week

Adult Crohn's Disease and Ulcerative Colitis

Initial dose (Day 1) is 160 mg (four 40 mg injections in one day, two 80 mg injections in one day, or one 80 mg injection per day for two consecutive days, or two 40 mg injections per day for two consecutive days), followed by 80 mg two weeks later (Day 15). Two weeks later (Day 29) begin a maintenance dose of 40 mg every other week.

Adult Hidradenitis Suppurativa

Initial dose (Day 1) is 160 mg (four 40 mg injections in one day, two 80 mg injections in one day, or one 80 mg injection per day for two consecutive days, or two 40 mg injections per day for two consecutive days), followed by 80 mg two weeks later (Day 15). Two weeks later (Day 29) begin a maintenance dose of 40 mg every week.

Plaque Psoriasis or Uveitis

80 mg initial dose followed by 40 mg every other week starting one week after initial dose.

Pediatric Crohn's Disease

	17 kg to <40kg OR 37 lbs to <88 lbs	≥40kg OR ≥ 88 lbs
Day 1	80 mg x1 (Two 40mg injections in one day)	160mg x1 (Four 40mg injections in one day or two 40mg injections for 2 days)
Day 15	40 mg x1	80mg x1
Day 29	20 mg every other week	40mg every other week

CONTRAINDICATION/ EXCLUSIONS/DISCONTINUATION

- Therapy may be discontinued if the patient is noncompliant with medical or pharmacological therapy **OR** the patient demonstrates clinically significant improvement in condition after initiation of Humira therapy
- The patient is receiving additional biologic DMARD therapy

CONTINUED ON THE NEXT PAGE

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ADALIMUMAB (MICHIGAN MEDICAID)

SPECIAL CONSIDERATIONS

- Additional information may be required on a case-by-case basis to allow for adequate review
- Aminosalicylates, corticosteroids, methotrexate, nonsteroidal anti-inflammatory drugs, analgesics, immunomodulatory agents (e.g., 6-mercaptopurine, azathioprine), and/or other non-biologic DMARDs may be continued during treatment with Humira therapy
- Black Box Warning (BBW): Increased risk of serious infections and malignancy

REFERENCES

- Humira [Prescribing Information]. North Chicago, IL: AbbVie Inc.; August 2018.
- McLaren Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ADMELOG SOLOSTAR (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
INSULIN LISPRO	ADMELOG SOLOSTAR		96719	BRAND NAME = ADEMLOG SOLOSTAR

This drug requires a written request for non-formulary exception for patients over the age of 21.

GUIDELINES FOR USE

INSULIN PEN CRITERIA:

The non-formulary exception guideline for **ADMELOG SOLOSTAR** requires the following:

- The patient is 21 years of age or younger **OR**
- The patient has a physical disability that causes the patient to be unable to draw up insulin from a vial into a syringe.

According to the information included on the request, this patient does not meet the medical necessity requirements for insulin pens. The formulary alternative for this patient is Admelog vials. If the patient's physical condition changes in the future, you may submit a request with documentation of the changes to be reviewed.

FDA APPROVED INDICATIONS

Indicated to improve glycemic control in adults and pediatric patients 3 years and older with type 1 diabetes mellitus and adults with type 2 diabetes mellitus.

DOSAGE AND ADMINISTRATION

Individualize and adjust the dosage based on route of administration, the individual's metabolic needs, blood glucose monitoring results and glycemic control goal.

REFERENCES

- Admelog [Prescribing Information]. Bridgewater, NJ; Sanofi-aventis U.S. LLC; Nov 2018.

Created: 01/19

Effective: 02/01/19

Client Approved: 01/16/19

P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ALISKIREN & ALISKIREN-HYDROCHLOROTHIAZIDE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
ALISKIREN, ALISKIREN- HYDROCHLOROTHIAZIDE	TEKTURNA, TEKTURNA- HCT	34493 35338		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA: The guideline named **ALISKIREN & ALISKIREN-HYDROCHLOROTHIAZIDE (Tekturna, Tekturna-HCT)** requires a diagnosis of mild to moderate hypertension. In addition, the following criteria must be met:

- The patient is 18 years of age or older
- There is documentation (e.g. medical records, physician attestation, technician review of relevant patient fill history) that the patient has tried and failed or had an intolerance to **TWO** of the following: Thiazide diuretic, ACE inhibitor, ARB, beta blocker, **OR** calcium channel blocker

RENEWAL CRITERIA:

The guideline named **ALISKIREN & ALISKIREN-HYDROCHLOROTHIAZIDE (Tekturna, Tekturna-HCT)** requires a diagnosis of mild to moderate hypertension. In addition, the following criteria must be met:

- The patient currently meets **ALL** initial coverage criteria
- The patient demonstrates adherence to therapy at least 85% of the time as verified by Prescriber and member's medication fill history (review Rx history for compliance), including:
 - Compliance in taking the medication as prescribed
 - No intolerable adverse effects or drug toxicity

[NOTE: Therapy may be discontinued due to poor adherence upon recommendation of the Medical Director when adherence < 85% has been demonstrated in at least two months during the course of therapy]
- The patient demonstrates disease stabilization or improvement:
 - Maintenance therapy may be authorized when therapy has demonstrated efficacy as evidenced by an improvement in disease activity after initial therapy

RATIONALE

To ensure appropriate use of Tekturna and Tekturna-HCT is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

TEKTURNA is indicated in the treatment of hypertension in adults and children 6 years of age and older, to lower blood pressure.

TEKTURNA-HCT is indicated for the treatment of hypertension, to lower blood pressure.

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

**CONTINUED ON NEXT PAGE
ALISKIREN & ALISKIREN-HYDROCHLOROTHIAZIDE (MICHIGAN MEDICAID)**

DOSAGE AND ADMINISTRATION

TEKTURNA

The recommended starting dose of Tekturna in adult patients is 150mg orally once daily. The dose may be increased to 300mg in patients whose blood pressure is not adequately controlled.

For pediatric patients the recommended dose is as follows:

Weight	Recommended Dose
20kg to 50kg	75mg once daily (maximum recommended dose is 150mg)
≥ 50kg	150mg once daily (same recommendation as in adults)

TEKTURNA-HCT

The recommended once-daily doses of Tekturna-HCT in order of increasing mean effect are: 150/12.5mg, 150/25mg or 300/12.5mg, and 300/25mg.

The antihypertensive effect of Tekturna-HCT is largely manifested within 1 week, with maximal effects generally seen around 4 weeks. If blood pressure remains uncontrolled after 2 to 4 weeks of therapy, the dose may be titrated up to a maximum of 300/25mg once daily.

For further dosage and administration details, please refer to the Prescribing Information for Tekturna and Tekturna-HCT.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Poor response to treatment as evidenced by physical findings and/or clinical symptoms following the initial 12 weeks approval for coverage
- Intolerable adverse effects or drug toxicity
- Persistent and uncorrectable problems with adherence to treatment
- Drug therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy
- No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

SPECIAL CONSIDERATIONS

Adverse Effects:

- A concern is hypotension that is not reversed when the drug is stopped due to the strong binding of renin and the long half-life of aliskiren (24-30 hrs).
- Aliskiren still is detectable in the kidneys up to 3 weeks after discontinuation.
- Doses greater than 300mg did not give an increased blood pressure response but increased the rate of diarrhea.
- Rate of cough was 1.1%, which was about one-half to one-third the rate of cough seen with ACE inhibitors.
- Two cases of angioedema with respiratory symptoms and two cases of periorbital edema without respiratory symptoms were noted. Therefore angioedema occurred in 0.06% of patients.
- Increases in potassium were uncommon (0.9% compared with 0.6% with placebo). However, the rate of hyperkalemia is expected to be greater if aliskiren is combined with an ACE inhibitor.

CONTINUED ON NEXT PAGE

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ALISKIREN & ALISKIREN-HYDROCHLOROTHIAZIDE (MICHIGAN MEDICAID)

Cautions:

- Experience with the use of aliskiren in patients with severe renal impairment is limited and therefore, caution is warranted. It does not appear to have an effect on serum creatinine, but data is lacking to confirm this.

Indications:

- The majority of trials included patients with mild to moderate hypertension.
- Limited data suggest that aliskiren also could be safe in severe hypertension as part of a combination therapy strategy.

Efficacy:

- Overall data from studies show aliskiren to be superior to placebo and similar or better efficacy compared with other commonly used agents.
- Aliskiren directly inhibits rennin while other antihypertensives target the rennin-angiotensin system.
- Has not been studied with maximal dose of ACE inhibitors.
- Modestly lowers blood pressure when used as monotherapy and has shown to have additive effects when combined with a thiazide diuretic or an ARB.
- Aliskiren has not been shown to improve clinical outcomes as seen with ACE inhibitors and ARB's in heart failure, coronary artery disease and renal disease therefore should only be used for hypertension at this time

REFERENCES

- Tekturna [Prescribing Information]. Boston, MA: Noden Pharma USA Inc.; November 2017.
- Tekturna-HCT [Prescribing Information]. Boston, MA: Noden Pharma USA Inc.; November 2016.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at:
https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

APIXABAN (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
APIXABAN	ELIQUIS	37792		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **APIXABAN (Eliquis)** requires that the medication is used for the reduction of risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, DVT prophylaxis in a patient undergoing knee or hip replacement surgery, or treatment of DVT, pulmonary embolism (PE), or for the reduction in the risk of recurrence of DVT or PE. In addition, the following criteria must be met:

For reduction of risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, approval requires documentation (e.g. labs, medical record, special studies and/or physician attestation) of the following:

- Request for Eliquis 5mg oral BID dosing requires documentation (e.g. labs, medical record, special studies and/or physician attestation) of the following:
 - The patient was started on Eliquis therapy in the hospital and was discharged while on the therapy
 - The patient has diagnosis of non-valvular atrial fibrillation
 - The patient has tried and failed or is intolerant to warfarin therapy
 - The patient has moderate to high risk of stroke as determined by the following:
 - History of stroke, TIA, or non-CNS systemic embolism, OR
 - 2 or more of the following risk factors:
 - Age of 75 years or older
 - Arterial hypertension requiring treatment
 - Diabetes mellitus
 - Heart failure of NYHA Class 2 or greater
 - Left Ventricular Ejection Fraction equal to or less than 40%
- Request for Eliquis 2.5mg oral dosing requires that the criteria for 5mg BID dosing are met AND documentation (e.g. labs, medical record, special studies and/or physician attestation) that patient has at least 2 of the following:
 - Age of 80 years or older
 - Body weight equal to or less than 60kg
 - Serum creatinine equal to or greater than 1.5mg/Dl

For DVT prophylaxis in a patient undergoing knee or hip replacement surgery, approval requires:

- The patient is 18 years of age or older
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of ALL of the following:
 - The patient was started on Eliquis therapy in the hospital and was discharged while on the therapy
 - The patient has undergone or will undergo total hip arthroplasty or total knee arthroplasty

CONTINUED ON NEXT PAGE

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

APIXABAN (MICHIGAN MEDICAID)

For treatment of DVT, pulmonary embolism (PE), approval requires:

- The patient is 18 years of age or older
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of ALL of the following:
 - The patient was started on Eliquis therapy in the hospital and was discharged while on the therapy
 - The patient has DVT or PE
 - The patient has tried and failed or is intolerant to warfarin therapy

For the reduction in the risk of recurrence of DVT or PE, no extra criteria are required for approval.

RENEWAL CRITERIA:

The guideline named **APIXABAN (Eliquis)** requires that the medication is used for the reduction of risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, or for the reduction in the risk of recurrence of DVT or PE. In addition, there must be documentation that the patient meets the following:

- The patient is tolerating and responding to medication and there continues to be a medical need for the medication
- The patient's CrCL is being monitored

RATIONALE

To ensure appropriate use of apixaban (Eliquis) is consistent with FDA approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS:

Eliquis is a factor Xa inhibitor anticoagulant indicated:

- To reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation (AF).
- For the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients who have undergone hip or knee replacement surgery.
- For the treatment of DVT and PE
- For the reduction in the risk of recurrent DVT and PE following initial therapy

DOSAGE AND ADMINISTRATION:

Non-valvular atrial fibrillation: The recommended dose is 5 mg taken orally twice daily.

In patients with at least 2 of the following characteristics: age \geq 80 years, body weight \leq 60 kg, or serum creatinine \geq 1.5 mg/dL, the recommended dose is 2.5 mg orally twice daily.

DVT Prophylaxis following hip or knee replacement surgery: 2.5 mg taken daily.

- In patients undergoing hip replacement surgery, the recommended duration of treatment is 35 days.
- In patients undergoing knee replacement surgery, the recommended duration of treatment is 12 days.

CONTINUED ON NEXT PAGE

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

APIXABAN (MICHIGAN MEDICAID)

Treatment of DVT and PE: The recommended dose is 10 mg taken orally twice daily for 7 days, followed by 5 mg taken orally twice daily.

Reduction in the risk of recurrent DVT and PE following initial therapy: The recommended dose is 2.5 mg taken orally twice daily, the recommended duration of treatment is 6 months.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

- **Box Warning:**
 - Discontinuing Eliquis can lead to higher risk of stroke. If discontinuation is warranted for reasons other than pathological bleeding, consider use of another anticoagulation agent.
 - Administration of Eliquis while also receiving neuraxial anesthesia or undergoing spinal puncture can lead to epidural or spinal hematomas, which can result in long term or permanent paralysis.
- Eliquis should be discontinued at least 48 hours prior to elective surgery or invasive procedures with a moderate or high risk of unacceptable or clinically significant bleeding. Eliquis should be discontinued at least 24 hours prior to elective surgery or invasive procedures with a low risk of bleeding or where the bleeding would be non-critical in location and easily controlled. Restart after the procedure once adequate hemostasis has been established
- Geriatric patients \geq 65 years old should avoid Eliquis if CrCl $<$ 25 ml/min
- The safety and efficacy of Eliquis has not been studied in patients with prosthetic heart valves. Therefore, Eliquis is not recommended in these patients
- Severe hepatic impairment (child Pugh Class C)
- Eliquis is not recommended in pregnancy
- Eliquis is not recommended if nursing – discontinue drug or discontinue nursing
- Avoid use with P-gp and strong CYP3A4 inhibitors/inducers in patients who require the 2.5mg BID dose
- Active pathological bleeding
- Hypersensitivity reaction to Eliquis
- Patient is noncompliant with medical or pharmacologic therapy
- No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy

REFERENCE:

- Apixaban [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb; August 2014
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_5228_28_7.pdf [Accessed October 1, 2018].

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P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

APREMILAST (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
APREMILAST	OTEZLA	40967		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **APREMILAST (Otezla)** requires a diagnosis of moderate to severe plaque psoriasis, or psoriatic arthritis. In addition, the following criteria must be met as documented by labs, medical record, special studies and/or physician attestation:

For patients with moderate to severe plaque psoriasis, approval requires:

- The patient is 18 years of age or older
- Greater than 10% of body surface area involvement (unless hands, feet, head, neck, or genitalia are involved)
- The patient has had a trial and failure of at least **ONE** topical agent
- The patient has had a trial and failure of UVB or PUVA therapy or contraindication to therapy
- The patient has had a trial and failure of methotrexate for at least 3 consecutive months or contraindication/intolerance to methotrexate
- The patient has had a trial and failure to at least **ONE** additional systemic treatment (i.e., azathioprine, cyclosporine, or acitretin) or contraindication/intolerance to systemic treatment

For patients with psoriatic arthritis, approval requires:

- The patient is 18 years of age or older
- The patient has had a trial and failure of methotrexate for at least 90 consecutive days in the previous 120-day period, or contraindication/intolerance to methotrexate
- The patient has had a trial and failure of at least **ONE** other non-biologic DMARD (i.e., sulfasalazine, cyclosporine, hydroxychloroquine or leflunomide) as sequential monotherapy for 3 months each OR in combination for at least 3 months, OR has a contraindication/intolerance

RENEWAL CRITERIA:

The guideline named **APREMILAST (Otezla)** requires a diagnosis of moderate to severe plaque psoriasis or active psoriatic arthritis. In addition, the following criterion must be met as documented by labs, medical record, special studies and/or physician attestation:

- The patient continues to have a beneficial response to therapy

RATIONALE

To ensure appropriate use of Otezla is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

OTEZLA is indicated for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy and for adult patients with active psoriatic arthritis.

CONTINUED ON NEXT PAGE

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

APREMILAST (MICHIGAN MEDICAID)

DOSAGE AND ADMINISTRATION

OTEZLA initial dosage titration recommendation from Day 1 to Day 5 is as follows:

Day	AM dose	PM dose
1	10mg	
2	10mg	10mg
3	10mg	20mg
4	20mg	20mg
5	20mg	30mg
6 & thereafter	30mg	30mg

Following the 5-day titration, the recommended maintenance dosage is 30mg twice daily taken orally starting on Day 6. This titration is intended to reduce the gastrointestinal symptoms associated with initial therapy. Otezla can be administered without regard to meals. Do not crush, split, or chew the tablets.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Therapy may be discontinued if the patient is noncompliant with medical or pharmacological therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.
- Patient receiving additional biologic DMARD therapy.

REFERENCES

- Otezla [Prescribing Information]. Summit, NJ: Celgene Corporation; April 2018.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ATOVAQUONE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
ATOVAQUONE	MEPRON	06619		

This drug requires a written request for prior authorization.

CRITERIA:

The guideline named **ATOVAQUONE (Mepron)** requires use in prophylaxis or prevention of *Pneumocystis jirovecii* pneumonia (PCP), or acute oral treatment of mild to moderate PCP. In addition, the following criteria must be met:

- The patient is 13 years of age or older
- The requested medication is prescribed by or in consultation with an infectious disease specialist
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of failure of or contraindication to trimethoprim-sulfamethoxazole (TMP-SMZ [Bactrim])

RATIONALE

To ensure appropriate use of Mepron is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

Mepron oral suspension is a quinone antimicrobial drug indicated for:

- Prevention of *Pneumocystis jirovecii* pneumonia (PCP) in adults and adolescents aged 13 years and older who cannot tolerate trimethoprim-sulfamethoxazole (TMP-SMX).
- Treatment of mild-to-moderate PCP in adults and adolescents aged 13 years and older who cannot tolerate TMP-SMX.

Limitations of Use:

- Treatment of severe PCP (alveolar arterial oxygen diffusion gradient [(A-a)DO₂] >45 mm Hg) with MEPRON has not been studied.
- The efficacy of MEPRON in subjects who are failing therapy with TMP-SMX has also not been studied.

DOSAGE AND ADMINISTRATION

- Prevention of PCP: 1,500 mg (10 mL) once daily with food.
- Treatment of PCP: 750 mg (5 mL) twice daily with food for 21 days.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Patient is noncompliant with medical or pharmacologic therapy.
- No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.
- Hypersensitivity to atovaquone or any component of the formulation.

REFERENCES

- Mepron [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline; October 2017.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_5228_28_7.pdf [Accessed October 1, 2018].

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Page 22

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

AZTREONAM (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
AZTREONAM	CAYSTON	36792		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (CONTINUED)

INITIAL CRITERIA:

The guideline named **AZTREONAM (Cayston)** requires a diagnosis of Cystic Fibrosis confirmed by appropriate diagnostic or genetic testing. In addition, the following criteria must be met.

- The patient is 7 years of age or older
- Therapy is prescribed by or in consultation with a pulmonologist or specialist with experience in treating Cystic Fibrosis
- Documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of all of the following:
 - The patient is using bronchodilators which are administered prior to aztreonam
 - Confirmation of ***Pseudomonas aeruginosa*** in cultures of the airways confirmed by a copy of a positive sputum culture
 - Susceptibility results indicating that aztreonam is the only inhaled antibiotic to which the *Pseudomonas aeruginosa* is sensitive
 - Confirmation that member is not receiving treatment with other inhaled/nebulized antibiotics or inhaled/nebulized anti-infective agents, including alternating treatment schedules or as part of a cyclic rotation with TOBI®, OR **ONE** of the following is applicable:
 - The patient previously used TOBI® inhalation solution and experienced a clinically significant adverse drug reaction or an unsatisfactory therapeutic response.
 - The patient has contraindication/intolerance or medical condition(s) that prevents the use of TOBI® inhalation solution (e.g., patient is pregnant, allergy to tobramycin).
 - Sputum culture shows resistance to tobramycin.

RENEWAL CRITERIA:

The guideline named **AZTREONAM (Cayston)** requires a diagnosis of Cystic Fibrosis confirmed by appropriate diagnostic or genetic testing. In addition, there must be documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of ALL of the following:

- The patient currently meets ALL initial coverage criteria
- The patient is adherent to prescribed therapy
- Documentation of stabilization or improvement as evaluated by a pulmonologist or specialist with experience in treating cystic fibrosis

CONTINUED ON NEXT PAGE

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

AZTREONAM (MICHIGAN MEDICAID)

RATIONALE

To ensure appropriate use of Cayston consistent with FDA approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATION

CAYSTON® is indicated to improve respiratory symptoms in cystic fibrosis (CF) patients with *Pseudomonas aeruginosa*. Safety and effectiveness have not been established in pediatric patients below the age of 7 years, patients with FEV1 <25% or >75% predicted, or patients colonized with *Burkholderia cepacia*.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cayston and other antibacterial drugs, Cayston should be used only to treat patients with CF known to have *Pseudomonas aeruginosa* in the lungs.

DOSAGE AND ADMINISTRATION

The recommended dose of CAYSTON for both adults and pediatric patients 7 years of age and older is one single-use vial (75 mg of aztreonam) reconstituted with 1 mL of sterile diluent administered 3 times a day for a 28-day course (followed by 28 days off CAYSTON therapy). Dosage is not based on weight or adjusted for age. Doses should be taken at least 4 hours apart.

CAYSTON is administered by inhalation using an Altera® Nebulizer System. Patients should use a bronchodilator before administration of CAYSTON.

CONTRAINDICATION/EXCLUSION/DISCONTINUATION

- Less than 7 years of age
- FEV1 less than 25% or greater than 75% predicted
- Colonization with *Burkholderia cepacia*
- Non-FDA approved indications
- Hypersensitivity to aztreonam or any of its components
- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy

OTHER SPECIAL CONSIDERATIONS

Administer only with the Altera Nebulizer system.

REFERENCES

- Cayston [Prescribing Information]. Foster City, CA. Gilead Sciences, Inc.; May 2014.
- McLaren Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_5228_28_7.pdf [Accessed October 1, 2018].

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P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

BENZNIDAZOLE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
BENZNIDAZOLE	BENZNIDAZOLE	21759		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

CRITERIA:

The guideline named **BENZNIDAZOLE (Benznidazole)** requires a diagnosis of Chagas disease (American trypanosomiasis) due to *Trypanosoma cruzi*.

RATIONALE

To ensure appropriate use of Benznidazole consistent with FDA approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATION

Benznidazole tablets are indicated in pediatric patients 2 to 12 years of age for the treatment of Chagas disease (American trypanosomiasis) caused by *Trypanosoma cruzi*.

This indication is approved under accelerated approval based on the number of treated patients who became Immunoglobulin G (IgG) antibody negative against the recombinant antigens of T. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

DOSAGE AND ADMINISTRATION

The total daily dose for pediatric patients 2 to 12 years of age is 5 mg/kg to 8 mg/kg orally administered in two divided doses separated by approximately 12 hours, for a duration of 60 days.

REFERENCES

- Benznidazole [Prescribing Information]. Florham Park, NJ. Exeltis USA, Inc.; August 2017.
- McLaren Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

BRAND MEDICALLY NECESSARY

Generic	Brand	HICL	GCN	Exception/Other
VARIOUS	VARIOUS			

GUIDELINES FOR USE

CRITERIA:

Our guideline for **BRAND MEDICALLY NECESSARY MEDICATIONS** requires that this product is only covered for patients that have tried a generically equivalent medication within the previous 6 months (verified in prescription claims history or in submitted chart notes) and are unable to use the generic equivalent due to allergic reaction or therapeutic failure. Approval for brand medications when a generic equivalent exists requires documentation of allergic reaction or therapeutic failure associated with the use of the generic equivalent by reporting to the FDA on a MedWatch Form. Your physician did not provide the required information and therefore your request was not approved. Brand medications will not be approved for patients who report lesser efficacy as compared to the equivalent generic medication unless it would be clinically inappropriate to address efficacy with dose adjustment. In addition, a past trial of the brand medication is required to confirm better efficacy of the brand medication over the generic equivalent.

RATIONALE

The intent of this prior authorization is to encourage the use of cost-effective generically equivalent medications before considering coverage of brand medications.

REFERENCES

- MedWatch: The FDA Safety Information and Adverse Event Reporting Program. Available at <http://www.fda.gov/safety/medwatch/default.htm>. Accessed December 21, 2015.

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Client Approval: 10/22/18

P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

BUDESONIDE/FORMOTEROL (MICHIGAN MEDICAID)

Generic	Label name	HICL	GCN	Exception/Other
BUDESONIDE/ FORMOTEROL FUMARATE	SYMBICORT 80-4.5MCG SYMBICORT 160-4.5MCG		98499 98500	

This drug requires a written request for non-formulary exception.

GUIDELINES FOR USE

INITIAL CRITERIA:

The non-formulary exception guideline named **BUDESONIDE/ FORMOTEROL (SYMBICORT)** requires that the patient:

- Be over the age of 12 with a diagnosis of Chronic Obstructive Pulmonary Disease (COPD) and have had a documented trial and failure of Fluticasone-Salmeterol (generic for Airduo Respiclick) ; **OR**
- Be between the ages of 6 and 12 with a diagnosis of asthma; **OR**
- Be over the age of 12 with a diagnosis of Asthma and have had a documented trial and failure of ALL formulary preferred asthma agents: Fluticasone-Salmeterol (generic for Airduo Respiclick), Qvar Redihaler, and Pulmicort Flexhaler.

RENEWAL CRITERIA:

The non-formulary exception guideline named **BUDESONIDE/ FORMOTEROL (SYMBICORT)** requires a diagnosis of asthma or Chronic Obstructive Pulmonary Disease (COPD). In addition, there must be documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of ALL of the following:

- The patient currently meets ALL initial coverage criteria
- The patient is adherent to prescribed therapy
- Documentation of stabilization or improvement of symptoms.

FDA APPROVED INDICATIONS

Indicated for the treatment of asthma is patients aged 6 years and older and the maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

DOSAGE AND ADMINISTRATION

The recommended dosage of Symbicort in patients between the ages of 6 and 11 for the treatment of asthma is two inhalations of Symbicort 80/4.5 mcg twice daily. The recommended dosage of Symbicort in patients age 12 and older for the treatment of asthma or COPD is two inhalations of Symbicort 160/4.5 mcg twice daily.

REFERENCES:

1. Symbicort Prescribing Information. AstraZeneca LP; Wilmington, DE. Access December 2017.
2. Global Initiative for Chronic Obstructive Lung Disease. GOLD Guidelines Updated 2018. Accessed January 2019.

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Client Approval: 01/14/19

P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

BYETTA, BYDUREON, TRULICITY (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
EXENATIDE	BYETTA		24613 24614	
EXENATIDE MICROSPHERES	BYDUREON PEN BYDUREON BCISE		36352 44039	
DULAGLUTIDE	TRULICITY		37169 37171	

This drug requires a written request for non-formulary exception.

GUIDELINES FOR USE

INITIAL CRITERIA:

The non-formulary exception guideline for **GLP-1 ANALOGS (BYETTA, BYDUREON, TRULICITY)** requires a diagnosis of Type 2 Diabetes Mellitus. In addition, the following criteria must be met:

- The patient is 18 years of age or older
- There is documentation (labs, medical record, special studies and/or physician attestation) for **ALL** of the following:
 - The patient has had a trial, failure, or contraindication to metformin **AND TWO** preferred formulary oral diabetes agents: glipizide, glyburide, glimepiride, chlorpropamide, tolazamide, tolbutamide, alogliptin, pioglitazone, Tradjenta, Januvia, Invokana, Jardiance, Steglatro **OR** insulin and has not achieved adequate glycemic control (HbA1c greater than 7% after 3 continuous months of receiving maximal daily insulin doses)
 - The patient has had a trial, failure, or contraindication to **ALL** preferred formulary synthetic glucagon-like peptide-1 (GLP-1): Victoza and Ozempic

RENEWAL CRITERIA:

The non-formulary exception guideline named **GLP-1 ANALOGS (BYETTA, BYDUREON, TRULICITY)** requires a diagnosis of Type 2 Diabetes Mellitus. In addition, there must be documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of ALL of the following:

- The patient currently meets ALL initial coverage criteria
- The patient is adherent to prescribed therapy
- Documentation of stabilization or improvement of symptoms

FDA APPROVED INDICATIONS

Indicated as adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

DOSAGE AND ADMINISTRATION

Byetta: Inject 5mcg within 60 minutes prior to morning and evening meals (approximately 6 or more hours apart). May increase to 10mcg twice daily after 1 month based on clinical response.

Bydureon/Bydureon Bcise: Inject 2mg by subcutaneous injection once every seven days (weekly), at any time of the day and with or without meals.

Trulicity: Inject 0.75mg subcutaneously once weekly at any time of day. Dose can be increased to 1.5mg once weekly for additional glycemic control.

CONTINUED ON NEXT PAGE

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

BYETTA, BYDUREON, TRULICITY (MICHIGAN MEDICAID)

REFERENCES

- Byetta [Prescribing Information]. Wilmington, DE, AstraZeneca Pharmaceuticals LP; Dec 2018.
- Bydureon [Prescribing Information]. Wilmington, DE, AstraZeneca Pharmaceuticals LP; Jan 2018.
- Trulicity [Prescribing Information]. Indianapolis, IN, Lilly USA, LLC; Aug 2017.

Created: 01/19

Effective: 02/01/19

Client Approval: 01/16/19

P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

CALCIPOTRIENE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
CALCIPOTRIENE	DOVONEX		1850 1852	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **CALCIPOTRIENE (Dovonex)** requires a documented (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) diagnosis of psoriasis. In addition, the following criteria must be met.

- The patient had a documented failure of two topical steroids, at least one of which must be high potency or very high potency

RENEWAL CRITERIA:

The guideline named **CALCIPOTRIENE (Dovonex)** requires a diagnosis of psoriasis. In addition, the following criteria must be met.

- There is documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of a positive response to therapy

RATIONALE

To ensure appropriate use of Dovonex consistent with FDA approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATION

Dovonex Cream, 0.005%, is indicated for the treatment of plaque psoriasis. The safety and effectiveness of topical calcipotriene in dermatoses other than psoriasis have not been established.

DOSAGE AND ADMINISTRATION

Apply a thin layer of Dovonex® Cream to the affected skin twice daily and rub in gently and completely. The safety and efficacy of Dovonex® Cream have been demonstrated in patients treated for eight weeks.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REFERENCES

- Dovonex [Prescribing Information]. Madison, NJ. Leo Pharma Inc.; June 2017.
- McLaren Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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Client Approval: 10/15/18

P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

CINACALCET (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
CINACALCET	SENSIPAR	25998		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **CINACALCET (Sensipar)** requires a diagnosis of Primary Hyperparathyroidism, Parathyroid Carcinoma or Secondary Hyperparathyroidism due to chronic kidney disease (CKD) requiring dialysis. In addition, the following criteria must be met:

For Primary Hyperparathyroidism or Parathyroid Carcinoma, approval requires:

- The patient is 18 years of age or older
- Sensipar is prescribed by or in consultation with a nephrologist or endocrinologist
- There is documentation of **ALL** the following labs: iPTH, calcium, renal function, serum phosphorous
 - iPTH levels must be > 300 pg/mL [(bio-intact parathyroid hormone) biPTH > 160] and Ca > 8.4 mg/dL in order to initiate therapy

For Secondary Hyperparathyroidism due to chronic kidney disease (CKD) requiring dialysis, approval requires:

- The patient is 18 years of age or older
- Sensipar is prescribed by or in consultation with a nephrologist or endocrinologist
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of **ALL** of the following:
 - A trial, failure, or intolerance to an approved formulary phosphate binder
 - A trial, failure, intolerance, or contraindication to calcitriol or Vitamin D analogs
 - ALL of the following labs: iPTH, calcium, renal function, serum phosphorous
 - iPTH levels must be > 300 pg/mL (biPTH > 160) and Ca > 8.4 mg/dL in order to initiate therapy

RENEWAL CRITERIA:

The guideline named **CINACALCET (Sensipar)** requires a diagnosis of Primary Hyperparathyroidism, Parathyroid Carcinoma or Secondary Hyperparathyroidism due to Chronic Kidney Disease (CKD) requiring dialysis. In addition, the following criteria must be met as documented by labs, medical record, special studies and/or physician attestation:

For Primary Hyperparathyroidism or Parathyroid Carcinoma, approval requires:

- The patient has serum calcium levels greater than 8.4 mg/dL

For Secondary Hyperparathyroidism due to Chronic Kidney Disease (CKD) on dialysis, approval requires:

- The patient has an iPTH > 150 pg/ml and serum calcium levels greater than 8.4 mg/dL

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

CINACALCET (MICHIGAN MEDICAID)

RATIONALE

To ensure appropriate use of Sensipar is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

SENSIPAR is indicated for the following:

- For the treatment of hypercalcemia in adult patients with Primary Hyperparathyroidism (HPT) for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy
- For the treatment of hypercalcemia in adult patients with Parathyroid Carcinoma
- Secondary Hyperparathyroidism (HPT) in adult patients with Chronic Kidney Disease (CKD) on dialysis

DOSAGE AND ADMINISTRATION

For patients with Primary Hyperparathyroidism or Parathyroid Carcinoma:

- The recommended starting dose is 30mg orally twice daily.
- The dose of Sensipar should be titrated every 2 to 4 weeks through sequential doses of 30mg twice daily, 60mg twice daily, and 90mg twice daily, and 90mg 3 or 4 times daily as necessary to normalize serum calcium levels.
- Serum calcium should be measured within 1 week after initiation or dose adjustment of Sensipar.

For patients with Secondary Hyperparathyroidism (HPT) in adult patients with Chronic Kidney Disease (CKD) on dialysis:

- The recommended starting dose is 30mg once daily.
- Serum calcium and serum phosphorus should be measured within 1 week and intact Parathyroid Hormone (iPTH) should be measured 1 to 4 weeks after initiation or dose adjustment of Sensipar.
- Sensipar should be titrated no more frequently than every 2 to 4 weeks through sequential doses of 30, 60, 90, 120 and 180mg once daily to target iPTH levels of 150 to 300pg/mL.

For further details regarding the dosage and administration, please refer to the Prescribing Information for Sensipar.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Hypersensitivity to any components of Sensipar
- Hypocalcemia
- Drug therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy
- Drug therapy may be discontinued if the patient demonstrates no clinically significant improvement in condition after initiation of drug therapy

REFERENCES

- Sensipar [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; May 2017.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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Client Approval: 12/06/18

P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

CLOBETASOL PROPIONATE 0.05% (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
CLOBETASOL PROPIONATE 0.05%	TEMOVATE	03327		DOSAGE FORM = CREAM, OINTMENT, SOLUTION

This drug requires a written request for prior authorization.

INITIAL/RENEWAL CRITERIA:

The guideline named **CLOBETASOLE PROPIONATE (Temovate)** requires a diagnosis of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. In addition, the following criteria must be met:

- The patient is 12 years of age or older.
- The patient has a documented (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) trial and failure of betamethasone dipropionate.

RATIONALE

To ensure appropriate use of clobetasol propionate 0.05% (Temovate) is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

CLOBETASOL PROPIONATE is a super high potency corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

DOSAGE AND ADMINISTRATION

Apply a thin layer of CLOBETASOL PROPIONATE cream, ointment or solution to the affected skin areas twice daily and rub in gently and completely.

Treatment beyond 2 consecutive weeks is not recommended, and the total dosage should not exceed 50 g/week because of the potential for the drug to suppress the hypothalamic-pituitary adrenal (HPA) axis. Use in pediatric patients under 12 years of age is not recommended.

As with other highly active corticosteroids, therapy should be discontinued when control has been achieved. If no improvement is seen within 2 weeks, reassessment of the diagnosis may be necessary.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy
- The patient demonstrates no clinically significant improvement in condition has occurred after initiation of drug therapy

REFERENCES

- Clobetasol propionate 0.05% cream [Prescribing Information]. Mahwah, NJ: Glenmark Pharmaceuticals, Inc.; May 2018.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_5228_28_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

DALFAMPRIDINE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
DALFAMPRIDINE	AMPYRA	13907		EXCLUDE ≠ MISCELL.; POWDER NON-DRUGS

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **DALFAMPRIDINE (Ampyra)** requires a documented diagnosis of multiple sclerosis with impaired walking ability. In addition, the following criteria must be met.

- Therapy is prescribed by or in consultation with a neurologist
- The patient is between 18 and 70 years old
- There is documentation of ALL of the following:
 - The patient is not wheelchair-bound
 - The patient does not have a history of seizures
 - The patient does not have moderate to severe renal impairment (Crcl < 50 ml/min)
 - The patient is on a disease modifying therapy for MS/confirmed diagnosis of MS
 - The patient has significant and continuous walking impairment that impairs ability to complete normal activities of daily living (such as meal preparation, household chores, etc.) attributable to ambulation or functional status despite optimal treatment for Multiple Sclerosis
 - The patient has a baseline 25-ft walking test between 8 and 45 seconds, OR the patient is ambulatory (i.e., does not require the use of a wheelchair [bilateral assistance is acceptable, such as a brace, cane, or crutch, as long as the patient can walk 20 meters without resting]) AND has Expanded Disability Status Scale (EDSS) score greater than or equal to 4.5 but less than 7

RENEWAL CRITERIA:

The guideline named **DALFAMPRIDINE (Ampyra)** requires documentation that the patient meets **ALL** of the following criteria:

- The patient currently meets ALL initial coverage criteria confirmed by documentation
- The patient is adherent to therapy at least 85% of the time as verified by member's medication fill history
- The patient's functional impairment resolved as a result of increased speed of ambulation resulting in the member being able to complete instrumental activities of daily living (such as meal preparation, household chores, etc.)
- The patient has improvement of at least 20% in timed walking speed as documented by the T25FW (timed 25-foot walk) from pre-treatment baseline

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

DALFAMPRIDINE (MICHIGAN MEDICAID)

RATIONALE

To ensure appropriate use of Ampyra consistent with FDA approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATION

AMPYRA is indicated as a treatment to improve walking in adult patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed.

DOSAGE AND ADMINISTRATION

The maximum recommended dosage of AMPYRA is one 10 mg tablet twice daily and should not be exceeded. Take doses approximately 12 hours apart. There is no evidence of additional benefit at doses greater than 10 mg twice daily. Adverse reactions, including seizures, and discontinuations because of adverse reactions were more frequent at higher doses.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- The patient does NOT have a diagnosis of spinal cord injury, myasthenia gravis, demyelinating peripheral neuropathies (such as Guillain -Barré syndrome), Alzheimer's disease, and Lambert Eaton myasthenic syndrome.
- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REFERENCE:

- Ampyra [Prescribing Information].]. Ardsley, NY. Acorda Therapeutics, Inc.; September 2017.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

DAPAGLIFLOZIN (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
DAPAGLIFLOZIN PROPANEDIOL	FARXIGA 5MG, FARXIGA 10MG		35698 34394	

This drug requires a written request for a NON-FORMULARY exception.

GUIDELINES FOR USE

INITIAL CRITERIA:

The non-formulary exception guideline for **DAPAGLIFLOZIN PROPANEDIOL (FARXIGA)** requires a diagnosis of Type 2 Diabetes Mellitus (DM). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- There is documentation (labs, medical record, special studies and/or physician attestation) for **ALL** of the following:
 - The patient has had a trial, failure, or contraindication to metformin **AND TWO** preferred formulary oral diabetes agents: glipizide, glyburide, glimepiride, chlorpropamide, tolazamide, tolbutamide, alogliptin, pioglitazone, Tradjenta, Januvia **OR** insulin and has not achieved adequate glycemic control (HbA1c greater than 7% after 3 continuous months of receiving maximal daily insulin doses)
 - The patient has had a trial, failure or contraindication to **ALL** preferred formulary sodium-glucose cotransporter-2 inhibitor (SGLT-2 inhibitor): Invokana, Jardiance and Steglatro

RENEWAL CRITERIA:

The non-formulary exception guideline named **DAPAGLIFLOZIN PROPANEDIOL (FARXIGA)** requires a diagnosis of Type 2 Diabetes Mellitus (DM). In addition, there must be documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of **ALL** of the following:

- The patient currently meets ALL initial coverage criteria
- The patient is adherent to prescribed therapy
- Documentation of stabilization or improvement of symptoms.

FDA APPROVED INDICATIONS

Indicated as adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

DOSAGE AND ADMINISTRATION

Recommended starting dose is 5mg by mouth once daily, taken in the morning, with or without food. Dose can be increased to 10mg once daily in patients tolerating Farxiga who require additional glycemic control

REFERENCES

- Farxiga [Prescribing Information]. Wilmington, DE, AstraZeneca Pharmaceuticals LP; Oct 2018.

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Effective: 02/01/19

Client Approval: 01/16/19

P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

DESMOPRESSIN ACETATE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
DESMOPRESSIN ACETATE	DDAVP STIMATE		26170 26173 26201	BRAND NAME ≠ DDAVP

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL/RENEWAL CRITERIA:

The guideline named **DESMOPRESSIN ACETATE (DDAVP, Stimate)** requires that the following criteria are met.

For request of Stimate, approval requires documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of **ONE** of the following:

- The patient has a diagnosis of hemophilia
- The patient has a diagnosis of von Willebrands disease Type 1

For request of DDAVP, approval requires documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of **BOTH** of the following:

- The patient has a diagnosis of diabetes insipidus
- The patient has had an inadequate response to a 3 month trial of a maximum tolerated dose or clinical contraindication to desmopressin tablets

RATIONALE

To ensure appropriate use of desmopressin acetate consistent with FDA approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATION

Stimate Nasal Spray:

- Indicated for patients with hemophilia A with Factor VIII coagulant activity levels greater than 5%. Desmopressin acetate will also stop bleeding in patients with hemophilia A with episodes of spontaneous or trauma-induced injuries such as hemarthroses, intramuscular hematomas or mucosal bleeding.
- Indicated for patients with mild to moderate classic von Willebrand's disease (Type I) with Factor VIII levels greater than 5%. Desmopressin acetate will also stop bleeding in mild to moderate von Willebrand's disease patients with episodes of spontaneous or trauma-induced injuries such as hemarthroses, intramuscular hematomas, mucosal bleeding or menorrhagia.

DDAVP nasal spray:

- DDAVP nasal spray is indicated as antidiuretic replacement therapy in the management of central diabetes insipidus in adults and pediatric patients 4 years of age and older.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

DESMOPRESSIN ACETATE (MICHIGAN MEDICAID)

DOSAGE AND ADMINISTRATION

Stimate Nasal Spray:

For both Hemophilia A and von Willebrand's disease, Stimate Nasal Spray is administered by nasal insufflation, one spray per nostril, to provide a total dose of 300 mcg. In patients weighing less than 50

kg, 150 mcg administered as a single spray provided the expected effect on Factor VIII coagulant activity, Factor VIII ristocetin cofactor activity and skin bleeding time. If Stimate Nasal Spray is used preoperatively, it should be administered 2 hours prior to the scheduled procedure.

DDAVP nasal spray

Central diabetes insipidus: The recommended dosage in adults is 10 mcg once daily into one nostril up to 40 mcg once daily (or 40 mcg divided into two or three daily doses). The recommended dosage in pediatric patients 4 years of age and older is 10 mcg once daily into one nostril. The dose can be titrated up to 30 mcg once daily (or 30 mcg divided into two daily doses, typically with 20 mcg given in the morning and 10 mcg given at nighttime). If administered more than once a day, adjust for an adequate diurnal rhythm of urine output.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Contraindicated in individuals with known hypersensitivity to desmopressin acetate or to any of its components.
- Contraindicated in patients with moderate to severe renal impairment (defined as a creatinine clearance below 50ml/min).
- Contraindicated in patients with hyponatremia or a history of hyponatremia.
- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.
- As of 2007, the intranasal formulation is no longer FDA-approved for the treatment of primary nocturnal enuresis.

REFERENCES

- Stimate [Prescribing Information]. King of Prussia, PA. CSL Behring LLC; July 2017.
- DDAVP [Prescribing Information]. Bridgewater, NJ. sanofi-aventis U.S. LLC; September 2009.
- McLaren Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_5228_28_7.pdf [Accessed August 20, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

DICLOFENAC (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
DICLOFENAC	SOLARAZE		86831	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **DICLOFENAC (Solaraze)** requires a diagnosis of actinic keratoses (AK). In addition, the following criteria must be met as documented by labs, medical record, special studies and/or physician attestation:

- The patient has had an inadequate response or intolerance to office-based treatments (liquid nitrogen cryotherapy, surgical curettage) OR has been considered and ruled out due to nature/number of lesions or limited resources to provide such treatments
- The patient has had an inadequate response to a full treatment or intolerance/contraindication to a trial of 5-fluorouracil
- The patient has had an inadequate response to a full treatment or intolerance/contraindication to a trial of imiquimod

RENEWAL CRITERIA:

The guideline named **DICLOFENAC (Solaraze)** requires a diagnosis of actinic keratoses (AK) and that the patient has experienced a positive response to Solaraze therapy for renewed approval.

RATIONALE

To ensure appropriate use of Solaraze is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

SOLARAZE is indicated for the topical treatment of actinic keratoses (AK).

DOSAGE AND ADMINISTRATION

- Solaraze Gel is applied to lesion areas twice daily; it is to be smoothed onto the affected area of the skin gently and the amount applied depends upon the size of the lesion site.
- Normally 0.5 grams of Solaraze Gel is used on each 5cm x 5cm lesion site.
- The recommended duration of therapy from 60 days to 90 days.
- Complete healing of the lesion(s) or optimal therapeutic effect may not be evident for up to 30 days following cessation of therapy.
- Lesions that do not respond to therapy should be carefully re-evaluated and management reconsidered.
- Sun avoidance is indicated during therapy.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Solaraze is contraindicated in patients with a known hypersensitivity to diclofenac.
- Solaraze should be used with caution in patients with active GI ulceration or bleeding and severe renal or hepatic impairments.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

DICLOFENAC (MICHIGAN MEDICAID)

- In addition, drug therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy.
- The patient demonstrates no clinically significant improvement in condition has occurred after initiation of drug therapy.

SPECIAL CONSIDERATIONS

- Pregnancy Category B

REFERENCES

- Solaraze [Prescribing Information]. New York, NY: PharmaDerm a division of Fougera Pharmaceuticals Inc.; April 2016.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

DIMETHYL FUMARATE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
DIMETHYL FUMARATE	TECFIDERA	40168		ROUTE=ORAL

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **DIMETHYL FUMARATE (Tecfidera)** requires a diagnosis of a relapsing form of multiple sclerosis (i.e., relapsing-remitting multiple sclerosis [RRMS], secondary-progressive multiple sclerosis [SPMS] with relapses, or progressive-relapsing multiple sclerosis [PRMS]). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- Tecfidera is prescribed by or in consultation with a board-certified neurologist, a board-certified multiple sclerosis or physician specialist with experience in prescribing multiple sclerosis therapy
- There is documentation (labs, medical record, special studies and/or physician attestation) of **ALL** the following:
 - Definitive diagnosis of a relapsing form of multiple sclerosis as defined by the McDonald criteria
 - Expanded Disability Status Scale (EDSS) score between 0 and 5 (disability severe enough to impair full daily activities) **OR** documentation supporting the disability within this range
 - The patient has had an inadequate response (to at least 6 months of therapy), intolerance, FDA labeled contraindication, or hypersensitivity to an interferon beta product (Avonex, Rebif, Betaseron, or Extavia) **AND** a non-interferon, glatiramer acetate (Copaxone)

[Note: (1) 'Needle phobia' or 'needle fatigue' is not considered an intolerance or contraindication to the first-line disease-modifying therapies (DMT's)

(2) Inadequate response is defined as meeting TWO of the following three criteria during treatment with one of these agents:

- ***Increase in frequency (at least two clinical relapses within the past 12 months), severity and/or sequelae of relapses***
- ***Changes in MRI: continues to have CNS lesion progression as measured by MRI (increased number or volume of gadolinium-enhancing lesions, T2 hyperintense lesions and/or T1 hypointense lesions)***

Note continued

- ***Increase in disability progression: Sustained worsening of EDSS score, routine neurological observation, mobility, OR ability to perform activities of daily living]***
- There is confirmation of **ONE** of the following from the prescriber **AND** by verifying the patient's prescription profile
 - The patient is not currently being treated with another disease-modifying agent for MS
 - The patient is currently being treated with another disease-modifying agent for MS **AND** the disease-modifying agent will be discontinued before starting the requested agent

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

DIMETHYL FUMARATE (MICHIGAN MEDICAID)

- The patient has **ALL** of the following baseline lab reports/exams
 - Baseline MRI [utilized to identify lesion progression (response to treatment) while on Tecfidera therapy]
 - The patient does not have a low lymphocyte count as documented by a recent (within 6 months) complete blood count (CBC) prior to initiating therapy
- [NOTE: Further CBC monitoring is recommended at least annually during therapy or as clinically necessary (based on signs and symptoms of infection).]***

RENEWAL CRITERIA:

The guideline named **DIMETHYL FUMARATE (Tecfidera)** requires a diagnosis of a relapsing form of multiple sclerosis (i.e., relapsing-remitting multiple sclerosis [RRMS], secondary-progressive multiple sclerosis [SPMS] with relapses, or progressive-relapsing multiple sclerosis [PRMS]). In addition, the following criteria must be met as documented by labs, medical record, special studies and/or physician attestation:

- Confirmation of **ONE** of the following from the prescriber **AND** by verifying in patients' prescription profile:
 - The patient is not currently being treated with another disease-modifying agent for MS
 - The patient is currently being treated with another disease-modifying agent for MS **AND** the disease-modifying agent will be discontinued before starting the requested agent
- The patient is adherent to therapy as verified by prescriber and patient's medication fill history (review prescription history for compliance)
[NOTE: Therapy may be discontinued due to compliance issues or poor adherence upon agreement among treating physician, member, and Medical Director]
- Complete blood count (CBC) within 6 months of starting the medication and at least annually or as clinically indicated during the course of treatment, because treatment with dimethyl fumarate may decrease lymphocyte counts (Dimethyl fumarate has not been studied in patient with pre-existing low lymphocyte counts)
- Stabilization or positive response to Tecfidera treatment as demonstrated by (including but not limited to the following): **[ALL APPLICABLE]**
 - **Relapses:** A decrease in frequency, severity, sequelae relapses from baseline
 - **Radiologic evidence of disease activity:** Beneficial effect on MRI measures of disease severity (decrease in number or volume of gadolinium-enhancing lesions, T2 hyperintense lesions and/or T1 hypointense lesions)
- Improved or stabilized disability progression: EDSS score remains less than or equal to 5.5 **OR** stabilization/improvement routine neurological observation, mobility, or ability to perform activities of daily living
- Validated patient-reported outcome measure [i.e. Fatigue Impact Scale (FIS), Medical Outcome Study SF-36, etc]
[Note: Fatigue Impact Scale (FIS) is a validated patient reported outcome measure that evaluates the effect of fatigue on the lives of people with MS. The Medical Outcome Study SF-36 is a self-administered health-reported quality of life outcome measure that is validated for several indications and patient populations.]

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

DIMETHYL FUMARATE (MICHIGAN MEDICAID)

RATIONALE

To ensure appropriate use of Tecfidera is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

TECFIDERA is indicated for the treatment of patients with relapsing forms of multiple sclerosis.

DOSAGE AND ADMINISTRATION

The following is the recommended dosage and administration for Tecfidera:

- The starting dose for Tecfidera is 120 mg orally twice daily.
- After 7 days, the dose should be increased to the maintenance dose of 240 mg orally twice daily.
- Temporary dose reductions to 120 mg twice daily may be considered for individuals who do not tolerate the maintenance dose.
- Within 4 weeks, the recommended dose of 240 mg twice daily should be resumed.
- Discontinuation of Tecfidera should be considered for patients unable to tolerate return to the maintenance dose.
- The incidence of flushing may be reduced by taking Tecfidera with food or taking non-enteric coated aspirin (up to a dose of 325 mg) 30 minutes prior to taking Tecfidera.
- Tecfidera should be swallowed whole and intact; it should not be crushed or chewed and the capsule contents should not be sprinkled on food.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Steady progression of disability
- Drug toxicity or serious adverse reaction
- Non-FDA approved indications
- Authorization will not be granted if ANY of the following Contraindications/Exclusions to Tecfidera therapy apply:
 - Hypersensitivity to Tecfidera or any ingredient in the formulation
 - History of significant gastrointestinal (GI) disease, chronic use of GI symptomatic therapy
 - Active malignancies
 - **NOTE:** 'Needle phobia' or 'needle fatigue' is not considered a contraindication.
- Concomitant therapy of any two disease modifying agents in MS
- Patient is noncompliant with medical or pharmacologic therapy
- No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy

SPECIAL CONSIDERATIONS

For use as monotherapy therapy only:

- Prescriber intends to use Tecfidera as a single agent
- No other disease-modifying multiple sclerosis medications are being administered concomitantly, including but not limited to: interferon beta-1a (Avonex, Rebif), interferon beta-1b (Betaseron, Extavia), glatiramer acetate (Copaxone), mitoxantrone (Novantrone), natalizumab (Tysabri), fingolimod (Gilenya), teriflunomide (Aubagio)

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

DIMETHYL FUMARATE (MICHIGAN MEDICAID)

REFERENCES

- Tecfidera [Prescribing Information]. Cambridge, MA: Biogen Inc.; June 2018.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at:
https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_5228_28_7.pdf [Accessed October 1, 2018].

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P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

DORNASE ALPHA (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
DORNASE ALPHA	PULMOZYME	08832		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **DORNASE ALPHA (Pulmozyme)** requires a diagnosis of cystic fibrosis (CF). In addition, the following must be met:

- The patient is 5 years of age or older
- Pulmozyme is prescribed by or in consultation with a pulmonologist or infectious disease specialist
- The patient has documentation (e.g. labs, medical record, special studies and/or physician attestation) to support the diagnosis of cystic fibrosis (CF)

RENEWAL CRITERIA:

The guideline named **DORNASE ALPHA (Pulmozyme)** requires a diagnosis of cystic fibrosis (CF). In addition, the following criteria must be met as documented by labs, medical record, special studies and/or physician attestation:

- Improved or stable FVC
- Disease stabilization
- Decreased incidence of respiratory infections

RATIONALE

To ensure appropriate use of Pulmozyme is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

PULMOZYME (dornase alfa) is indicated for daily administration in conjunction with standard therapies for the management of cystic fibrosis (CF) patients to improve pulmonary function.

In CF patients with an FVC \geq 40% of predicted, daily administration of PULMOZYME has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics.

DOSAGE AND ADMINISTRATION

PULMOZYME dosing recommendation for most cystic fibrosis patients is as follows: one 2.5 mg single-use ampule inhaled once daily using a recommended jet nebulizer/compressor system or eRapid™ Nebulizer System.

Some patients may benefit from twice-daily administration.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- PULMOZYME is not authorized for non-FDA-approved indication.
- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy.
- No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

DORNASE ALPHA (MICHIGAN MEDICAID)

SPECIAL CONSIDERATIONS

- Per FDA-approved label: PULMOZYME was studied in patients 3 months to 5 years of age; while clinical trial data are limited in patients <5 years, the use of Pulmozyme should be considered for pediatric patients with CF who may experience potential benefit in pulmonary function or who may be at risk of respiratory tract infection.

REFERENCES

- Pulmozyme [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; March 2018.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

DPP-4I/COMBINATION DPP-4 INHIBITORS (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
SITAGLIPTIN LINAGLIPTIN	JANUVIA TRADJENTA	34126 37576		
SITAGLIPTIN-METFORMIN SITAGLIPTIN-METFORMIN XR LINAGLIPTIN-METFORMIN	JANUMET JANUMET XR JENTADUETO	34665 38464		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **DPP-4/COMBINATION DPP-4 INHIBITORS** requires that the patient is 18 years of age or older. In addition, the following criteria must be met.

For request of single ingredient DPP-4 Inhibitors (i.e., Januvia, Tradjenta), approval requires:

- Requested medication is for the treatment of type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycemic control
- Documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of all of the following:
 - The patient has tried and failed metformin
 - The patient has tried and failed alogliptin
 - The patient's hemoglobin A1C is ≤ 9

For request of combination DPP-4 Inhibitors (i.e., Janumet, Janumet XR, Jentadueto), approval requires:

- Requested medication is to be used as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes mellitus when treatment with combination therapy is appropriate
- Documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of all of the following:
 - The patient has clinically demonstrated successful treatment with individual components for 60 of the most recent 120 days
 - The patient has tried and failed alogliptin-metformin
 - The patient's hemoglobin A1C is ≤ 9%

RENEWAL CRITERIA:

The guideline named **DPP-4/COMBINATION DPP-4 INHIBITORS** requires that the request is for the treatment of type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycemic control (for Januvia, Tradjenta), OR is to be used as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes mellitus when treatment with combination therapy is appropriate (for Janumet, Janumet XR, Jentadueto). In addition, the following criteria must be met.

- The patient is responding to treatment
- The patient is tolerating treatment

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

DPP-4I/COMBINATION DPP-4 INHIBITORS (MICHIGAN MEDICAID)

RATIONALE

To ensure appropriate use of DPP-4 inhibitors and Combination DPP-4 inhibitors are consistent with FDA approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

Januvia, Tradjenta: indicated as adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Janumet – indicated as adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both sitagliptin and metformin is appropriate.

Janumet XR – indicated as adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both sitagliptin and metformin extended release is appropriate.

Jentadueto – indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate.

DOSAGE AND ADMINISTRATION

DPP-4 inhibitors	Dosage
Januvia (sitagliptin) 25, 50, 100 mg tablets	25mg-100mg per day
Tradjenta (linagliptin) 5 mg tablet	5mg per day

DPP-4 inhibitors/Combination	Dosage
Janumet (sitagliptin/metformin) 50-500mg, 50-1000mg tablets	BID dosing NTE 100mg sitagliptin/ 2000mg metformin per day
Janumet XR (sitagliptin/metformin XR) 50-500mg,50-1,000mg,100-1000mg tablets	Once daily dosing NTE 100mg sitagliptin/ 2000mg metformin XR per day
Jentadueto (linagliptin/metformin) 2.5-500mg, 2.5-850mg, 2.5-1000mg tablets	BID dosing NTE 5mg linagliptin/ 2000mg metformin per day

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

DPP-4I/COMBINATION DPP-4 INHIBITORS (MICHIGAN MEDICAID)

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

Contraindication/Exclusion/Discontinuation:

- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REFERENCES

- Januvia [Prescribing Information]. Whitehouse Station, NJ: Merck & Co.; February 2018.
- Tradjenta [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharm; August 2017.
- Janumet [Prescribing Information]. Whitehouse Station, NJ: Merck & Co.; February 2018.
- Janumet XR [Prescribing Information]. Whitehouse Station, NJ: Merck & Co.; February 2018.
- Jentadueto [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharm; August 2017.
- McLaren Health Plan Common Formulary Prior Authorization Criteria. Available at:
https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_5228_28_7.pdf [Accessed August 20, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

DRONABINOL (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
DRONABINOL	MARINOL		27992 27990 27991	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **DRONABINOL (Marinol)** requires a diagnosis of chemotherapy induced nausea and vomiting or that the request is for appetite stimulation in patients with a documented diagnosis of AIDS with anorexia associated with weight loss. In addition, the following criteria must be met:

For the diagnosis of chemotherapy induced nausea and vomiting, approval requires:

- The requested medication is prescribed by or in consultation with an oncologist
- There is documentation (e.g., labs, medical records, special studies and/or physician attestation) of **ALL** of the following:
 - The patient is receiving chemotherapy
 - The patient is under close supervision during the initial use of Marinol and during dose adjustments due potential for altered mental status
 - The quantity of Marinol approved will be limited to the amount necessary for a single cycle of chemotherapy
 - The patient has had a trial and failure, intolerance, contraindication or is refractory to an emetic regimen consistent with the NCCN guidelines that includes a serotonin antagonist (ondansetron, granisetron), dexamethasone, promethazine, or prochlorperazine.

For requests for appetite stimulation in AIDS patients with anorexia associated with weight loss, approval requires:

- The requested medication is prescribed by or in consultation with an infectious disease specialist
- The patient is 18 years of age or older
- There is documentation (e.g., labs, medical records, special studies and/or physician attestation) of trial and failure, intolerance, or contraindication to Megestrol

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MCLAREN HEALTH PLAN MEDICAID PRIOR AUTHORIZATION GUIDELINES

DRONABINOL (MICHIGAN MEDICAID)

RENEWAL DENIAL TEXT: The guideline named **DRONABINOL (Marinol)** requires a diagnosis of chemotherapy induced nausea and vomiting or that the request is for appetite stimulation in a patient with a documented diagnosis of AIDS with anorexia associated with weight loss. In addition, the following criteria must be met:

Renewal for the diagnosis of chemotherapy induced nausea and vomiting, approval requires:

- There is documentation (e.g., labs, medical record, special studies and/or physician attestation) of decreased episodes of nausea and vomiting

Renewal for requests for appetite stimulation in AIDS patients with anorexia associated with weight loss, approval requires:

- There is documentation (e.g., labs, medical record, special studies and/or physician attestation) of response to treatment based on stabilization of the patient's weight

RATIONALE

To ensure appropriate use of Marinol is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

Marinol is a cannabinoid indicated in adults for the treatment of:

- Anorexia associated with weight loss in patients with AIDS.
- Nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.

DOSAGE AND ADMINISTRATION

Anorexia associated with weight loss in adult patients with AIDS

The recommended adult starting dosage is 2.5mg orally twice daily, one hour before lunch.

Nausea and vomiting associated with chemotherapy in adult patients who failed conventional antiemetics

The recommended starting dosage is 5mg/m², administered 1 to 3 hours prior to the administration of chemotherapy, then every 2 to 4 hours after chemotherapy, for a total of 4 to 6 doses per day.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Hypersensitivity to dronabinol, cannabinoids, sesame oil, or any component of the formulation.
- In addition, therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

OTHER SPECIAL CONSIDERATIONS

- Use cautiously in individuals with the following conditions as they may worsen with use of this product:
 - Seizure
 - Psychiatric disorders
 - Drug Abuse and dependence
 - Cardiovascular disorders

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

DRONABINOL (MICHIGAN MEDICAID)

REFERENCES

- Marinol [Prescribing Information]. North Chicago, IL: AbbVie Inc.; August 2017.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_5228_28_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ENOXAPARIN (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
ENOXAPARIN	LOVENOX		420 42071 42091 62771 62772 62773 70022	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **ENOXAPARIN (Lovenox)** requires a request for: prophylaxis of deep vein thrombosis (DVT) or pulmonary embolism (PE), treatment of acute deep vein thrombosis (DVT), bridge therapy for perioperative warfarin discontinuation, prophylaxis of thrombosis during pregnancy, prophylaxis of thrombosis in cancer patients at high risk of thrombosis, prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction, or treatment of acute ST-segment elevation myocardial infarction. In addition, the following criteria must be met:

For prophylaxis of deep vein thrombosis (DVT) or pulmonary embolism (PE), approval requires:

- The patient is 18 years of age or older
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of **ONE** of the following:
 - Patient is undergoing hip replacement surgery, during and following hospitalization
 - Patient is undergoing knee replacement surgery
 - Patient is undergoing abdominal surgery and the patient is at risk for thromboembolic complications
 - Patient is at risk for thromboembolic complications due to severely restricted mobility during acute illness
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of **BOTH** of the following:
 - The requested drug is medically necessary over formulary anticoagulants or warfarin due to a medical condition, contraindication/intolerance, or previous failure of formulary anticoagulants
 - There are no contraindications to therapy with the requested agent

For the treatment of acute deep vein thrombosis (DVT), approval requires:

- The patient is 18 years of age or older
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of **ONE** of the following:
 - Request is for inpatient with or without pulmonary embolism (PE), when administered in conjunction with warfarin sodium
 - Request is for outpatient without pulmonary embolism (PE), when administered in conjunction with warfarin sodium

(Initial criteria continued on next page)

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ENOXAPARIN (MICHIGAN MEDICAID)

- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of **BOTH** of the following:
 - The requested drug is medically necessary over formulary anticoagulants or warfarin due to a medical condition, contraindication/intolerance, or previous failure of formulary anticoagulants
 - There are no contraindications to therapy with the requested agent

For bridge therapy for perioperative warfarin discontinuation, approval requires:

- The patient is 18 years of age or older
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of **BOTH** of the following:
 - The requested drug is medically necessary over formulary anticoagulants or warfarin due to a medical condition, contraindication/intolerance, or previous failure of formulary anticoagulants
 - There are no contraindications to therapy with the requested agent

For prophylaxis of thrombosis during pregnancy, approval requires:

- The patient is 18 years of age or older
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of ALL of the following:
 - Use of subcutaneous (SQ) unfractionated heparin (UFH) is required in prophylaxis in pregnancy
 - The requested drug is medically necessary over formulary anticoagulants or warfarin due to a medical condition, contraindication/intolerance, or previous failure of formulary anticoagulants
 - There are no contraindications to therapy with the requested agent

For prophylaxis of thrombosis in cancer patients with high risk of thrombosis, approval requires:

- The patient is 18 years of age or older
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of **BOTH** of the following:
 - The requested drug is medically necessary over formulary anticoagulants or warfarin due to a medical condition, contraindication/intolerance, or previous failure of formulary anticoagulants
 - There are no contraindications to therapy with the requested agent

For prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction, approval requires:

- Concurrent administration with aspirin

For the treatment of acute ST-segment elevation myocardial infarction, approval requires:

- Concurrent administration with aspirin

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ENOXAPARIN (MICHIGAN MEDICAID)

RENEWAL CRITERIA:

The guideline named **ENOXAPARIN (Lovenox)** requires a request for prophylaxis of deep vein thrombosis (DVT) or pulmonary embolism (PE), treatment of acute deep vein thrombosis (DVT), bridge therapy for perioperative warfarin discontinuation, prophylaxis of thrombosis in cancer patients with high risk of thrombosis, prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction, or treatment of acute ST-segment elevation myocardial infarction. In addition, the following criteria must be met:

For prophylaxis of deep vein thrombosis (DVT) or pulmonary embolism (PE), treatment of acute deep vein thrombosis (DVT), bridge therapy for perioperative warfarin discontinuation, or prophylaxis of thrombosis in cancer patients with high risk of thrombosis, approval requires:

- The patient meets all of the initial criteria
- Bridge therapy and thrombosis prophylaxis would be considered for continued coverage but must be clearly outlined with length of treatment identified with explanation
- The length of renewal authorization is based on anticipated length of therapy, indication and/or recent INR if on warfarin

For prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction, or treatment of acute ST-segment elevation myocardial infarction, approval requires:

- The patient is tolerating and responding to therapy

RATIONALE

To ensure appropriate use of Lovenox is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

ENOXAPARIN is indicated for the following:

- Prophylaxis of deep vein thrombosis
 - In patients undergoing abdominal surgery who are at risk for thromboembolic complications
 - In patients undergoing hip replacement surgery, during and following hospitalization
 - In patients undergoing knee replacement surgery
 - In medical patients who are at risk for thromboembolic complications due to severely restricted mobility during acute illness
- Treatment of acute deep vein thrombosis
 - Inpatient with or without pulmonary embolism, when administered in conjunction with warfarin sodium
 - Outpatient without pulmonary embolism, when administered in conjunction with warfarin sodium
- Prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction, when concurrently administered with aspirin
- Treatment of acute ST-segment elevation myocardial infarction, when administered concurrently with aspirin

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ENOXAPARIN (MICHIGAN MEDICAID)

DOSAGE AND ADMINISTRATION

ENOXAPARIN dosing recommendation is as follows:

- Prophylaxis of deep vein thrombosis
 - In patients undergoing abdominal surgery who are at risk for thromboembolic complications
40mg once a day
 - In patients undergoing hip replacement surgery, during and following hospitalization
40mg once a day
 - In patients undergoing knee replacement surgery
30mg every 12 hours
 - In medical patients who are at risk for thromboembolic complications due to severely restricted mobility during acute illness
40mg once a day
- Treatment of acute deep vein thrombosis
 - Inpatient with or without pulmonary embolism, when administered in conjunction with warfarin sodium
1mg/kg every 12 hours or 1.5mg/kg once a day
 - Outpatient without pulmonary embolism, when administered in conjunction with warfarin sodium
1mg/kg every 12 hours
- Prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction, when concurrently administered with aspirin
1mg/kg every 12 hours in conjunction with aspirin therapy (100mg to 325mg once daily)
- Treatment of acute ST-segment elevation myocardial infarction, when administered concurrently with aspirin

DOSAGE AND ADMINISTRATION (CONTINUED)

Single intravenous bolus of 30mg plus a 1mg/kg subcutaneous dose, followed by 1mg/kg subcutaneously every 12 hours (max 100mg for the first two doses only, followed by 1mg/kg dosing for the remaining doses). In conjunction with aspirin therapy (75mg to 325mg once daily) unless contraindicated.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy
- No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy
- Box Warning: Spinal/Epidural hematomas:
 - Epidural or spinal hematomas may occur in patients who are anticoagulated with LMWHs or heparinoids and are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures.
 - Factors that can increase the risk of developing epidural or spinal hematomas in these patients include use of indwelling epidural catheters; concomitant use of other drugs that affect hemostasis, such as nonsteroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, and other anticoagulants; a history of traumatic or repeated epidural or spinal punctures; and a history of spinal deformity or spinal surgery. Optimal timing between the administration of enoxaparin and neuraxial procedures is not known.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ENOXAPARIN (MICHIGAN MEDICAID)

- Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary.
- Consider the benefits and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis.

SPECIAL CONSIDERATIONS

- Enoxaparin is used in bridging to warfarin in a number of situations which require INR monitoring

REFERENCES

- Lovenox [Prescribing Information]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; October 2017.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ESA - DARBEPOETIN ALFA (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
DARBEPOETIN ALFA	ARANESP	22890		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **DARBEPOETIN ALFA (Aranesp)** requires a diagnosis of anemia associated with chronic kidney disease (CKD) or anemia due to the effects of concomitantly administered cancer chemotherapy. In addition, the following criteria must be met:

For diagnosis of anemia associated with chronic kidney disease, approval requires:

- Hemoglobin < 10 g/dL within the last 2 weeks
- Iron studies showing patient has adequate iron stores to support erythropoiesis (e.g., ferritin > 100 ng/mL, transferrin saturation > 20%)

For diagnosis of anemia due to the effects of concomitantly administered cancer chemotherapy, approval requires:

- Hemoglobin < 10 g/dL within the last 2 weeks
- Documentation to support anemia is due to concomitant myelosuppressive chemotherapy **AND** the patient is currently receiving chemotherapy
- The patient has a diagnosis of non-myeloid malignancy (e.g., solid tumor)
- The patient has a minimum of 2 additional months of planned chemotherapy upon initiation of Aranesp therapy

RENEWAL CRITERIA: The guideline named **DARBEPOETIN ALFA (Aranesp)** requires diagnosis of anemia associated with chronic kidney disease (CKD) or anemia due to the effects of concomitantly administered cancer chemotherapy. In addition, the following criteria must be met:

- Hemoglobin < 11 g/dL within the last 2 weeks
- Follow up iron studies showing patient has adequate iron to support erythropoiesis

RATIONALE

To ensure appropriate use of Aranesp is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

- **CHRONIC KIDNEY DISEASE:** The prescribing information (PI) of the ESAs and an FDA safety update recommend initiation of therapy only for patients with a hgb of < 10g/dL. They recommend reducing or interrupting the dose of ESA and using the lowest dose of an ESA sufficient to reduce the need for blood transfusions at a hgb of 11g/dL for patients on dialysis or a hgb of 10g/dL for patients not on dialysis.
- **ANEMIA RELATED TO CANCER CHEMOTHERAPY:** ASCO recommends initiating ESA therapy at hgb levels < 10g/dL while NCCN recommends initiation at or below hgb levels of 11g/dL. ASCO recommends maintaining hgb levels between 10 and 12 g/dL, while NCCN does not comment on a maintenance hgb range.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ESA - DARBEPOETIN ALFA (MICHIGAN MEDICAID)

DOSAGE AND ADMINISTRATION

For the treatment of anemia due to:

- Chronic Kidney Disease (CKD) in patients on dialysis and patients not on dialysis
- The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy

Recommended starting dose:

- CKD on dialysis: 0.45mcg/kg IV/SC as a weekly injection or 0.75mcg/kg once every 2 weeks as appropriate.
- CKD not on dialysis: 0.45mcg/kg IV/SC given once at 4-week intervals as appropriate
- Cancer chemotherapy:
 - 2.25mcg/kg SC every week until completion of a chemotherapy course
 - 500 mcg every 3 weeks SC until completion of a chemotherapy course

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Anemia in patients with cancer who are not receiving chemotherapy
- Anemia associated with acute myelogenous leukemias (AML), chronic myelogenous leukemias (CML) or other myeloid cancers
- Anemia associated with radiotherapy (as monotherapy) in cancer
- To enhance athletic performance
- Substitute for red blood cell transfusions in patients who require immediate correction of anemia (i.e. acute blood loss)

REFERENCES

- Aranesp [Prescribing Information]. Thousand Oaks, CA: Amgen; January 2018.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_5228_28_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ESA - EPOETIN ALFA (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
EPOETIN ALFA	PROCRIT, EPOGEN	04553		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL DENIAL TEXT: The guideline named **EPOETIN ALFA (Procrit/Epogen)** requires a diagnosis of chronic kidney disease, anemia due to the effects of concomitantly administered cancer chemotherapy, anemia related to zidovudine therapy, or that the requested therapy is being used for the reduction of allogeneic RBC transfusion in a patient undergoing elective, noncardiac, or nonvascular surgery. In addition, the following criteria must be met:

For diagnosis of anemia associated with chronic kidney disease, approval requires:

- Hemoglobin < 10 g/dL within the last 2 weeks
- Iron studies showing patient has adequate iron stores to support erythropoiesis (e.g., ferritin > 100 ng/mL, transferrin saturation > 20%)

For diagnosis of anemia due to the effects of concomitantly administered cancer chemotherapy, approval requires:

- Hemoglobin < 10 g/dL within the last 2 weeks
- Documentation to support anemia is due to concomitant myelosuppressive chemotherapy **AND** the patient is currently receiving chemotherapy
- The patient has a diagnosis of non-myeloid malignancy (e.g., solid tumor)
- The patient has a minimum of 2 additional months of planned chemotherapy upon initiation of Epogen/Procrit therapy

For patients undergoing elective, noncardiac, or nonvascular surgery, approval requires:

- The patient has a hemoglobin > 10 g/dL and < 13 g/dL within 30 days prior to the planned surgery date

For diagnosis of anemia related to zidovudine therapy, approval requires:

- The patient is receiving treatment with zidovudine at a dose < 4200 mg/week
- BOTH of the following
 - Endogenous erythropoietin levels < 500 mUnits/mL
 - Hemoglobin < 10 g/dL within the last 2 weeks

RENEWAL CRITERIA:

The guideline named **EPOETIN ALFA (Procrit/Epogen)** requires a diagnosis of chronic kidney disease, anemia due to the effects of concomitantly administered cancer chemotherapy, anemia related to zidovudine therapy, or that the patient is undergoing elective, noncardiac, or nonvascular surgery. In addition, the following criteria must be met:

- The patient has a hemoglobin < 11 g/dL within the last 2 weeks
- Follow up iron studies showing patient has adequate iron stores to support erythropoiesis

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ESA - EPOETIN ALFA (MICHIGAN MEDICAID)

RATIONALE

To ensure appropriate use of Procrit/Epogen is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

- CHRONIC KIDNEY DISEASE: The prescribing information (PI) of the ESAs and an FDA safety update recommend initiation of therapy only for patients with a hgb of < 10g/dL. They recommend reducing or interrupting the dose of ESA and using the lowest dose of an ESA sufficient to reduce the need for blood transfusions at a hgb of 11g/dL for patients on dialysis or a hgb of 10g/dL for patients not on dialysis.
- ANEMIA RELATED TO CANCER CHEMOTHERAPY: ASCO recommends initiating ESA therapy at hgb levels < 10g/dL while NCCN recommends initiation at or below hgb levels of 11g/dL. ASCO recommends maintaining hgb levels between 10 and 12 g/dL, while NCCN does not comment on a maintenance hgb range.
- ANEMIA RELATED TO ZIDOVUDINE THERAPY: The clinical trials contained within the PI of the ESAs recommend initiating therapy at a hgb of less than 10g/dL and maintaining between 10 and 12g/dL.
- PATIENTS SCHEDULED FOR ELECTIVE, NONCARDIAC, NONVASCULAR SURGERY: The PI of the ESAs recommends therapy only for those patients with a hgb level at or below 13g/dL.

DOSAGE AND ADMINISTRATION

Epogen/Procrit

- Reduction of allogeneic RBC transfusions in patients undergoing elective, noncardiac, nonvascular surgery
- Treatment of anemia due to:
 - Chronic Kidney Disease (CKD) in patients on dialysis and not on dialysis
 - Zidovudine in HIV-infected patients
 - The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy

Recommended starting dose:

- CKD on dialysis:
 - Adults: 50-100 units/kg 3 times weekly
 - Pediatrics: 50 units/kg 3 times weekly
- CKD not on dialysis:
 - Adult patients: 50-100 units/kg 3 times weekly
- Zidovudine-treated HIV-infected patients
 - Adults: 100 units/kg 3 times per week
- Cancer chemotherapy:
 - Adults: 150 units/kg SC 3 times per week until completion of a chemotherapy course, or 40,000 units SC weekly until completion of a chemotherapy course
 - Pediatrics: 600 units/kg IV until completion of a chemotherapy course
- Surgery:
 - 300 units/kg per day SC for 15 days total: administered daily for 10 days before surgery, on the day of surgery, and for 4 days after surgery
 - 600 units/kg SC in 4 doses administered 21, 14, and 7 days before surgery and on the day of surgery

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ESA - EPOETIN ALFA (MICHIGAN MEDICAID)

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Anemia in patients with cancer who are not receiving chemotherapy
- Anemia associated with acute myelogenous leukemias (AML), chronic myelogenous leukemias (CML) or other myeloid cancers
- Anemia associated with radiotherapy (as monotherapy) in cancer
- To enhance athletic performance
- Substitute for red blood cell transfusions in patients who require immediate correction of anemia (i.e. acute blood loss)
- Uncontrolled hypertension; pure red cell aplasia (PRCA) that begins after treatment with epoetin alfa or other erythropoietin protein drugs; serious allergic reactions to epoetin alfa
- Increased mortality, myocardial infarction, stroke, and thromboembolism

REFERENCES

- Procrit [Prescribing Information]. Thousand Oaks, CA: Amgen, July 2018.
- Epogen [Prescribing Information]. Thousand Oaks, CA: Amgen, July 2018.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_5228_28_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ETANERCEPT (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
ETANERCEPT	ENBREL		23574 52651 98398	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **ETANERCEPT (Enbrel)** requires a diagnosis of ankylosing spondylitis (AS), moderate to severe chronic plaque psoriasis (PsO), psoriatic arthritis (PsA), moderately to severely active rheumatoid arthritis (RA), or moderate to severe polyarticular juvenile idiopathic arthritis (JIA). In addition, the following criteria must be met.

For patients with a diagnosis of ankylosing spondylitis (AS), approval requires:

- Therapy is prescribed by or in consultation with a rheumatologist
- The patient is 18 years of age or older
- There is documentation (e.g., Labs, Medical Records, Special studies and/or Physician Attestation) of ALL the following:
 - a) Current negative TB test
 - b) The patient has had a previous trial and failure or contraindication to **TWO** different NSAIDS within the last 60 days
 - c) The patient has had a trial and failure of or contraindication to sulfasalazine

For patients with a diagnosis of moderate to severe chronic plaque psoriasis (PsO), approval requires:

- The patient is 4 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- There is documentation (e.g., Labs, Medical Records, Special studies and/or Physician Attestation) of ALL the following criteria:
 - a) Current negative TB test
 - b) Greater than 15% of body surface area involvement (unless hands, feet, head, neck, or genitalia are involved)
 - c) The patient has had a previous trial and failure or contraindication to at least one topical agent
 - d) The patient has had a previous trial and failure, contraindication, or intolerance to at least TWO systemic treatments (azathioprine, cyclosporine)
 - e) The patient has had a previous trial and failure or contraindication to UVB or PUVA therapy
 - f) The patient has had a previous trial and failure, contraindication, or intolerance to methotrexate for at least 3 consecutive months

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ETANERCEPT (MICHIGAN MEDICAID)

For the diagnosis of psoriatic arthritis (PsA), approval requires:

- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- The patient is 18 years of age or older
- There is documentation (e.g., Labs, Medical Records, Special studies and/or Physician Attestation) of BOTH the following:
 - a) The patient has had a previous trial and failure or contraindication to one DMARD other than methotrexate (e.g., sulfasalazine, hydroxychloroquine or leflunomide)
 - b) The patient has had a previous trial and failure of or contraindication to methotrexate for at least 3 months

For the diagnosis of moderately to severely active rheumatoid arthritis (RA), approval requires:

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- There is documentation (e.g., Labs, Medical Records, Special studies and/or Physician Attestation) that the patient has had a previous trial and failure, contraindication or intolerance to methotrexate and at least 1 other oral DMARD (sulfasalazine, hydroxychloroquine or leflunomide) as sequential monotherapy for 3 months each or in combination for at least 3 months

For the diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (JIA), approval requires:

- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- There is documentation (e.g., Labs, Medical Records, Special studies and/or Physician Attestation) of a trial and failure, contraindication or intolerance to at least 3 consecutive months of methotrexate

RENEWAL CRITERIA:

The guideline named **ETANERCEPT (Enbrel)** requires a diagnosis of ankylosing spondylitis (AS), psoriatic arthritis (PsA), moderately to severely active rheumatoid arthritis (RA), or moderate to severe polyarticular juvenile idiopathic arthritis (JIA), or moderate to severe chronic plaque psoriasis (PsO) for renewal. In addition, the following criteria must be met.

- Documentation that all criteria required for initiation of treatment continue to be met
- Documentation that the patient is compliant and continues to have a beneficial response to Enbrel therapy

RATIONALE

To ensure appropriate use of Enbrel consistent with FDA approved indications and Michigan Medicaid requirements.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ETANERCEPT (MICHIGAN MEDICAID)

FDA APPROVED INDICATION

Enbrel is a tumor necrosis factor (TNF) blocker indicated for the treatment of:

- Rheumatoid Arthritis (RA)
- Polyarticular Juvenile Idiopathic Arthritis (PJIA) in patients aged 2 years and older
- Psoriatic Arthritis (PsA)
- Ankylosing Spondylitis (AS)
- Plaque Psoriasis (PsO) in patients aged 4 years of age or older

DOSAGE AND ADMINISTRATION

Enbrel is administered by subcutaneous injection.

- Adult RA and PsA: 50mg once weekly with or without methotrexate (MTX)
- AS: 50mg once weekly
- Adult PsO: 50mg twice weekly for 3 months, followed by 50mg once weekly
- Pediatric PsO or PJIA: 0.8mg/kg weekly, with a maximum of 50mg per week

CONTRAINDICATION/EXCLUSION/DISCONTINUATION:

Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REFERENCES

- Enbrel [Prescribing Information]. Thousand Oaks, CA. Immunex Corporation; November 2017.
- McLaren Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

EZETIMIBE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
EZETIMIBE	ZETIA	24459		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL/RENEWAL CRITERIA:

The guideline named **EZETIMIBE (Zetia)** requires a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH), Homozygous Sitosterolemia, mixed Primary Hyperlipidemia, or Primary (heterozygous familial and non-familial) hyperlipidemia.

In addition, the following must be met:

For patients with Primary (heterozygous familial and non-familial) hyperlipidemia or Homozygous Sitosterolemia, approval requires:

- The requested medication will be used as monotherapy
- The patient has documentation (e.g. labs, medical record, special studies and/or physician attestation) of ONE the following:
 - The patient has active liver disease
 - The patient has unexplained, persistent elevations of liver enzymes
 - The patient has hypersensitivity or contraindication to statin therapy
 - The patient has intolerance to trial of two separate statins, defined as dose-limiting side effects (e.g. myalgia, myopathy, neuropathy, elevated CPK levels) related to current statin therapy
 -

For patients with Homozygous Familial Hypercholesterolemia (HoFH), mixed Primary Hyperlipidemia or Primary (heterozygous familial and non-familial) hyperlipidemia, approval requires:

- The requested medication will be used as combination therapy
- The patient has documentation (e.g. labs, medical record, special studies and/or physician attestation) of both of the following:
 - The patient is adherent to current statin therapy for at least 60 days in the previous 120 days
 - The patient meets **ONE** of the following:
 - The patient has had an inadequate response to atorvastatin 80mg **OR**
 - The patient has had an inadequate response or dose-limiting side effects (e.g. myalgia, myopathy, neuropathy, elevated CPK levels) to atorvastatin and a maximally tolerated dose of another statin other than atorvastatin

RATIONALE

To ensure appropriate use of ezetimibe (Zetia) consistent with FDA-approved indications and Michigan Medicaid requirements.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

EZETIMIBE (MICHIGAN MEDICAID)

FDA APPROVED INDICATIONS

ZETIA is approved for the following indications:

Primary Hyperlipidemia as either monotherapy or combination therapy:

- 1) Monotherapy in patients with primary (heterozygous familial and non-familial) hyperlipidemia and adjunctive to diet for the reduction of elevated total cholesterol (total-C), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), and non-high-density lipoprotein cholesterol (LDL-C).
- 2) Combination therapy with a HMG-CoA Reductase Inhibitor (statin) in patients with primary (heterozygous familial and non-familial) hyperlipidemia OR with fenofibrate in patients with mixed hyperlipidemia.

FDA APPROVED INDICATIONS (CONTINUED)

Homozygous Familial Hypercholesterolemia (HoFH) as combination therapy with atorvastatin or simvastatin, for the reduction of elevated total-C and LDL-C levels, OR as adjunct to other lipid-lowering treatments (e.g., LDL apheresis).

Homozygous Sitosterolemia as an adjunctive therapy to diet for the reduction of elevated sitosterol and acampesterol levels in patients with homozygous familial sitosterolemia.

Limitation of Use:

- ZETIA has not been studied in the treatment of Fredrickson Type I, III, IV and V dyslipidemias.
- ZETIA's effectiveness on cardiovascular morbidity and mortality has not been determined.

DOSAGE AND ADMINISTRATION

The recommended dose of ZETIA is 10mg orally once daily, with or without food.

REFERENCES

- Zetia [Prescribing Information]. Whitehouse Station, NJ: MERCK & CO., INC.; February 2016.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_5228_28_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

FEBUXOSTAT (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
FEBUXOSTAT	ULORIC	36106		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **FEBUXOSTAT (Uloric)** requires a diagnosis of chronic management of hyperuricemia in patients with gout. In addition, the following must be met:

- The patient is 18 years of age or older
- The patient has documentation (e.g. labs, medical record, special studies and/or physician attestation) of **ALL** the following criteria:
 - The patient has evidence of gout with hyperuricemia
 - The patient has tried and failed or is intolerant to gout-hyperuricemia treatment with another xanthine oxidase inhibitor (allopurinol)
 - The patient has had an adequate trial and failure of preferred formulary agent or contraindication to preferred formulary agent (e.g. colchicine, probenecid)
 - For specific requests of febuxostat 80 mg tablets; the patient must have serum uric acid levels that are greater than 6mg/dL after 2 weeks of newly initiated therapy

RENEWAL CRITERIA:

The guideline named **FEBUXOSTAT (Uloric)** requires a diagnosis of gout. In addition, the following must be met:

For the chronic management of hyperuricemia in patients with gout, approval requires:

- The patient has documentation (e.g. labs, medical record, special studies and/or physician attestation) of **BOTH** the following:
 - The patient has a demonstrable decrease in or cessation of gouty flares
 - The patient has **ONE** of the following:
 - A serum uric acid level less than 6mg/dL following 2 weeks of therapy **OR**
 - A serum uric acid level greater than 6mg/dL following 2 weeks of therapy at 40mg daily dosing with the intent to increase to the maximum dosing of 80mg daily

RATIONALE

To ensure appropriate use of febuxostat (Uloric) is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

ULORIC is a xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in patients with gout. Uloric is not recommended for the treatment of asymptomatic hyperuricemia.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

FEBUXOSTAT (MICHIGAN MEDICAID)

DOSAGE AND ADMINISTRATION

- The recommended dosage of Uloric for the treatment of hyperuricemia in patients with gout is 40mg or 80mg orally once daily. The recommended starting dose is 40mg once daily. However, for patients who do not achieve a serum uric acid level less than 6mg/dL after two weeks with the 40mg dose, then the Uloric 80mg dose is recommended.
- No dose adjustment is necessary in patients with mild to moderate renal impairment.
- A recommended dose of Uloric 40mg once daily is recommended in patients with severe renal impairment.
- No dose adjustment is necessary in patients with mild to moderate hepatic impairment.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Excluded for the treatment of asymptomatic hyperuricemia
- Contraindicated in patients being treated with azathioprine or mercaptopurine
- Not approved in conditions where urate levels are greatly increased due to malignancy
- Patient is noncompliant with medical or pharmacologic therapy
- No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy

SPECIAL CONSIDERATIONS

- Caution in patients with severe hepatic impairment (Child-Pugh Class C)
- Caution in patients with severe renal impairment (CrCl less than 30 mL/min)

REFERENCES

- Uloric [Prescribing Information]. Deerfield, IL: Takeda Pharmaceuticals; February 2018.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_5228_28_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

FENTANYL TRANSDERMAL PATCH (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
FENTANYL TRANSDERMAL PATCH	DURAGESIC		19200 19201 19202 19203 24635	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **FENTANYL TRANSDERMAL PATCH (Duragesic)** requires that the request is for the management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. In addition, the following criteria must be met.

- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with a board-certified pain management physician
- There is documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of ALL of the following:
 - Chronic pain condition must be present and documented
 - The patient has tried and failed one other long acting opioid analgesic on the Common Formulary
 - The requested medication is intended for regular, around-the-clock use, not PRN
 - Based on the patient's narcotic history, the use of the requested medication is deemed safe

RENEWAL CRITERIA:

The guideline named **FENTANYL TRANSDERMAL PATCH (Duragesic)** requires that the request is for the management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. In addition, there must be documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of BOTH of the following:

- The patient meets all of the initial criteria
- The patient is responsive to treatment

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

FENTANYL TRANSDERMAL PATCH (MICHIGAN MEDICAID)

RATIONALE

To ensure appropriate use of Duragesic consistent with FDA approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATION

Duragesic is indicated for the management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Patients considered opioid-tolerant are those who are taking, for one week or longer, at least 60 mg morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid.

Limitations of Use:

- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve Duragesic for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Duragesic is not indicated as an as-needed (prn) analgesic.

DOSAGE AND ADMINISTRATION

Duragesic should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain. Do not initiate treatment with in opioid nontolerant patients.

The recommended starting dose when converting from other opioids to Duragesic is intended to minimize the potential for overdosing patients with the first dose. Discontinue or taper all other around-the-clock opioid drugs when Duragesic therapy is initiated.

The dosing interval is 72 hours. Individually titrate Duragesic to a dose that provides adequate analgesia and minimizes adverse reactions. Continually reevaluate patients receiving DURAGESIC to assess the maintenance of pain control and the relative incidence of adverse reactions, as well as monitoring for the development of addiction, abuse, or misuse. Do not increase the dose for the first time until at least 3 days after the initial application. Titrate the dose based on the daily dose of supplemental opioid analgesics required by the patient on the second or third day of the initial application.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

FENTANYL TRANSDERMAL PATCH (MICHIGAN MEDICAID)

CONTRAINDICATION/EXCLUSION/DISCONTINUATION

- **Fentanyl patches are not intended for use when the following situations are present:**
 - Significant respiratory depression, especially in unmonitored settings
 - Acute or severe bronchial asthma
 - Current or suspected paralytic ileus
 - Known hypersensitivity to fentanyl or any components of Duragesic
 - Management of acute pain or in patients who require opioid analgesia for a short period of time
 - Management of post-operative pain, including use after out-patient or day surgeries (e.g., tonsillectomies)
 - Management of mild pain
 - Management of intermittent pain (e.g., use on an as needed basis [PRN])
- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

OTHER SPECIAL CONSIDERATIONS

- **Limitations of use:** Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release (ER) opioid formulations, reserve fentanyl for use in patients for whom alternative treatment options (e.g., non-opioid analgesics, immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.

REFERENCES

- Duragesic [Prescribing Information]. Titusville, NJ. Janssen Pharmaceuticals, Inc.; June 2017.
- McLaren Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_5228_28_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

FINGOLIMOD (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
FINGOLIMOD	GILENYA		29073	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **FINGOLIMOD (Gilenya)** requires the diagnosis of a relapsing form of multiple sclerosis (i.e., relapsing-remitting multiple sclerosis [RRMS], secondary-progressive multiple sclerosis [SPMS], or progressive-relapsing multiple sclerosis [PRMS]). In addition, the following criteria must be met:

- The patient is 18 years of age and older
- The requested medication is prescribed by or in consultation with a board-certified neurologist, board-certified multiple sclerosis specialist **OR** a physician specialist with experience in prescribing multiple sclerosis therapy
- The patient has documentation (e.g. labs, medical record, special studie and/or physician attestation) of **ALL** the following:
 - A definitive diagnosis of a relapsing form of multiple sclerosis as defined by the McDonald criteria
 - The patient has an Expanded Disability Status Scale (EDSS) score between 0 and 5 (disability severe enough to impair full daily activities) **OR** documentation supporting the disability within this range
 - The patient has had an inadequate response to (minimum of 6 months of therapy), intolerance, FDA labeled contraindication, or hypersensitivity to an interferon beta product (Avonex, Rebif, Betaseron, or Extavia) **AND** glatiramer acetate (Copaxone)
 - Confirmation of **ONE** of the following from the prescriber **AND** by verifying the member's prescription profile:
 - The patient is not currently being treated with another disease-modifying agent for MS
 - The patient is currently being treated with another disease-modifying agent for MS **AND** the disease-modifying agent will be discontinued before the start of the requested agent
 - The patient has **ALL** of the following labs or exams within the last 6 months: CBC, LFT's and bilirubin levels, negative pregnancy if female, EKG evaluation, and ophthalmic examination
 - The patient has documented history of chicken pox **OR** has had the varicella zoster vaccination **OR** has evidence of immunity (positive antibodies)

RENEWAL CRITERIA: The guideline named **FINGOLIMOD (Gilenya)** requires the diagnosis of a relapsing form of multiple sclerosis (i.e., relapsing-remitting multiple sclerosis [RRMS], secondary-progressive multiple sclerosis [SPMS], or progressive-relapsing multiple sclerosis [PRMS]). In addition, the following documentation (e.g. labs, medical record, special studies and/or physician attestation) is required for renewed approval:

- Confirmation of **ONE** of the following from the prescriber **AND** by verifying the member's prescription profile:
 - The patient is not currently being treated with another disease-modifying agent for MS
 - The patient is currently being treated with another disease-modifying agent for MS **AND** the disease-modifying agent will be discontinued before the start of the requested agent

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

FINGOLIMOD (MICHIGAN MEDICAID)

RENEWAL CRITERIA CONTINUED:

- The patient is compliant with therapy as verified by prescriber and patient's medication fill history (review prescription history for compliance)
- The patient has **ALL** of the following labs or exams: CBC, LFT's and bilirubin levels, negative pregnancy if female, EKG evaluation and ophthalmic examination
- The patient has continued stabilization or positive response to Gilenya therapy as documented by (including but not limited to the following):
 - The patient has a decrease in frequency, severity, sequelae relapses from baseline **OR**
 - The patient has radiological evidence of disease activity as shown by a beneficial effect on MRI measures of disease severity (a decrease in number or volume of gadolinium-enhancing lesions, T2 hyperintense lesions and/or T1 hypointense lesions)
- The patient has **ONE** of the following improvement outcomes
 - An EDSS score that remains less than or equal to 5.5
 - Stabilization or improvement in routine neurological observation, mobility, or ability to perform activities of daily living
- The patient has a validated reported outcome measure [i.e. Fatigue Impact Scale (FIS), Medical Outcome Study SF-36, etc]

RATIONALE

To ensure appropriate use of Fingolimod (Gilenya) is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

GILENYA is indicated for the treatment of relapsing forms of multiple sclerosis (MS) in patients 10 years of age and older.

DOSAGE AND ADMINISTRATION

- **Adults and pediatric patients** (10 years of age and older weighing more than 40 kg): 0.5 mg orally once-daily, with or without food
- **Pediatric patients** (10 years of age and above weighing less than or equal to 40 kg): 0.25 mg orally once-daily, with or without food.

Pediatric patients 10 -17 years of age are to go through the manufacturer's Gilenya Go Program for the 0.25mg dose

GILENYA doses higher than 0.5mg are associated with greater incidences of adverse reactions without additional benefit.

Initiation of Gilenya results in a decrease in heart rate, for which monitoring is recommended prior to dosing and at the end of the observation period; obtain an electrocardiogram (ECG) in all patients. First dose administration of Gilenya should be done in a setting with resources to appropriately manage symptomatic bradycardia. Please refer to the Prescribing Information for Gilenya for further details.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

FINGOLIMOD (MICHIGAN MEDICAID)

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Steady progression of disability
- Drug toxicity or serious adverse reaction
- Non-FDA approved indications
- Myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Class III/IV heart failure experienced within the past 6 months
- History or presence of Mobitz Type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless patient has a functioning pacemaker
- Baseline QTc interval \geq 500 msec
- Treatment with Class Ia or Class III anti-arrhythmic drugs
[Note: "Needle phobia" or "needle fatigue" is not considered a contraindication]
- Therapy may be discontinued if the patient is noncompliant with medical or pharmacological therapy **OR** the patient demonstrates clinically significant improvement in condition after initiation of drug therapy

SPECIAL CONSIDERATIONS

- The prescriber intended to use Gilenya as monotherapy only; and no other disease-modifying multiple sclerosis medications are being administered concomitantly, including but not limited to:
 - Interferon beta-1a (Avonex, Rebif)
 - Interferon beta-1b (Betaseron, Extavia)
 - Glatiramer acetate (Copaxone)
 - Mitoxantrone (Novantrone)
 - Natalizumab (Tysabri)
 - Teriflunomide (Aubagio)
 - Dimethyl fumarate (Tecfidera)

REFERENCES

- Gilenya [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2018.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

FLUOROURACIL (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
FLUOROURACIL CREAM	CARAC, EFUDEX		12514 30781	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **FLUOROURACIL (Carac, Efudex)** requires a diagnosis of actinic keratosis or superficial basal cell carcinoma. In addition, there must be documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of the following:

- The patient has an inadequate response or intolerance to office -based treatments (liquid nitrogen cryotherapy, surgical curettage) OR have been considered and ruled out as options due to the nature/number of lesions or limited resources to provide such treatments
- The patient has an inadequate response to a full treatment or intolerance/contraindication to a trial of imiquimod

RENEWAL CRITERIA:

The guideline named **FLUOROURACIL (Carac, Efudex)** requires a diagnosis of actinic keratosis or superficial basal cell carcinoma. In addition, the following criterion must be met.

- Documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) that the patient has recurrence of active lesions and treatment with another course of therapy is required

RATIONALE

To ensure appropriate use of fluorouracil consistent with FDA approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATION

Carac: Carac is indicated for the topical treatment of multiple actinic or solar keratoses of the face and anterior scalp.

Efudex: Recommended for the topical treatment of multiple actinic or solar keratoses. In the 5% strength, it is also useful in the treatment of superficial basal cell carcinomas when conventional methods are impractical, such as with multiple lesions or difficult treatment sites. Safety and efficacy in other indications have not been established.

DOSAGE AND ADMINISTRATION

Carac: Carac cream should be applied once a day to the skin where actinic keratosis lesions appear, using enough to cover the entire area with a thin film. Carac cream should not be applied near the eyes, nostrils, or mouth. Carac cream should be applied 10 minutes after thoroughly washing, rinsing, and drying the entire area. Carac cream may be applied using the fingertips. Immediately after application, the hands should be thoroughly washed. Carac cream should be applied up to 4 weeks as tolerated. Continued treatment up to 4 weeks results in greater lesion reduction. Local irritation is not markedly increased by extending treatment from 2 to 4 weeks and is generally resolved within 2 weeks of cessation of treatment.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

FLUOROURACIL (MICHIGAN MEDICAID)

DOSAGE AND ADMINISTRATION (CONTINUED)

Efudex:

- **Actinic or Solar Keratosis:** Apply cream or solution twice daily in an amount sufficient to cover the lesions. Medication should be continued until the inflammatory response reaches the erosion stage, at which time use of the drug should be terminated. The usual duration of therapy is from 2 to 4 weeks. Complete healing of the lesions may not be evident for 1 to 2 months following cessation of Efudex therapy.
- **Superficial Basal Cell Carcinomas:** Only the 5% strength is recommended. Apply cream or solution twice daily in an amount sufficient to cover the lesions. Treatment should be continued for at least 3 to 6 weeks. Therapy may be required for as long as 10 to 12 weeks before the lesions are obliterated. As in any neoplastic condition, the patient should be followed for a reasonable period of time to determine if a cure has been obtained.

CONTRAINDICATION/EXCLUSION/DISCONTINUATION

- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REFERENCES

- Carac [Prescribing Information]. Bridgewater, NJ. Valeant Pharmaceuticals North America LLC; May 2017.
- Efudex [Prescribing Information]. Bridgewater, NJ. Valeant Pharmaceuticals North America LLC; May 2017.
- McLaren Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed August 20, 2018].

Created: 11/18

Effective: 01/01/19

Client Approval: 10/15/18

P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

FLUTICASONE/ SALMETEROL DISKUS (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
FLUTICASONE/ SALMETEROL	ADVAIR DISKUS		50584 50594 50604	

This drug requires a written request for NON-FORMULARY exception.

GUIDELINES FOR USE

INITIAL CRITERIA:

The non-formulary exception guideline for **FLUTICASONE/ SALMETEROL DISKUS (ADVAIR DISKUS)** requires that the patient:

- Be between the ages of 4 and 12 years old and have a diagnosis of Asthma; **OR**
- Be over the age of 12 years old with a diagnosis of Asthma and have had a documented trial and failure to all formulary agents: Fluticasone-Salmeterol (generic for Airduo Respiclick), Pulmicort Flexhaler, and Qvar Redihaler; or have a documented reason why the patient would be unable to use the formulary agents; **OR**
- Be over the age of 12 years old with a diagnosis of Chronic Obstructive Pulmonary Disease (COPD) and have had a documented trial and failure with Fluticasone-Salmeterol (generic for Airduo Respiclick).

RENEWAL CRITERIA:

The non-formulary exception guideline named **FLUTICASONE/ SALMETEROL DISKUS (ADVAIR DISKUS)** requires a diagnosis of asthma or Chronic Obstructive Pulmonary Disease (COPD). In addition, there must be documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of ALL of the following:

- The patient currently meets ALL initial coverage criteria
- The patient is adherent to prescribed therapy
- Documentation of stabilization or improvement of symptoms.

FDA APPROVED INDICATIONS

Indicated for the treatment of asthma is patients aged 4 years and older and the maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive pulmonary disease (COPD).

DOSAGE AND ADMINISTRATION

The recommended dosage of Advair Diskus in patients between the ages of 4 and 11 years old for the treatment of asthma is one inhalation of Advair Diskus 100/50 mcg twice daily. The recommended dosage of Advair Diskus in patients age 12 and older for the treatment of asthma is one inhalation of Advair Diskus 100/50, 250/50 or 500/50 mcg twice daily. The recommended dosage for the maintenance treatment of COPD is 1 inhalation of Advair Diskus 250/50 mcg twice daily.

REFERENCES

- Advair Diskus [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline.; Dec 2017.

Created: 01/19

Effective: 02/01/19

Client Approval: 01/15/19

P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

FLUTICASONE/ SALMETEROL HFA (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
FLUTICASONE/ SALMETEROL	ADVAIR HFA		97135 97136 97137	

This drug requires a written request for NON-FORMULARY exception.

INITIAL CRITERIA:

The non-formulary exception guideline for **FLUTICASONE/ SALMETEROL HFA (ADVAIR HFA)** requires that the patient:

- Be over the age of 12 years old with a diagnosis of Chronic Obstructive Pulmonary Disease (COPD) and have had a documented trial and failure with Fluticasone-Salmeterol (generic for Airduo Respiclick); **OR**
- Be over the age of 12 years old with a diagnosis of Asthma and have had a documented trial and failure to all formulary agents: Fluticasone-Salmeterol (generic for Airduo Respiclick), Pulmicort Flexhaler, and Qvar Redihaler; or have a documented reason why the patient would be unable to use the formulary agents.

RENEWAL CRITERIA:

The non-formulary exception guideline named **FLUTICASONE/ SALMETEROL HFA(ADVAIR HFA)** requires a diagnosis of asthma or Chronic Obstructive Pulmonary Disease (COPD). In addition, there must be documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of ALL of the following:

- The patient currently meets ALL initial coverage criteria
- The patient is adherent to prescribed therapy
- Documentation of stabilization or improvement of symptoms.

FLUTICASONE/ SALMETEROL HFA (MICHIGAN MEDICAID)

FDA APPROVED INDICATIONS

Indicated for the treatment of asthma is patients aged 12 years.

DOSAGE AND ADMINISTRATION

The recommended dosage of Advair HFA (all strengths) is 2 inhalations twice daily in patients over the age of 12 for the treatment of asthma.

REFERENCES

- Advair HFA [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline.; Dec 2017.

Created: 01/19

Effective: 02/01/19

Client Approval: 01/15/19

P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

GRANULOCYTE COLONY STIMULATING FACTORS (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
TBO-FILGRASTIM	GRANIX	40426		
FILGRASTIM	NEUPOGEN	06070		
FILGRASTIM-SNDZ	ZARXIO	41814		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA FOR GRANIX:

The guideline named **GRANULOCYTE COLONY STIMULATING FACTORS (Granix)** requires the request is for treatment of chemotherapy-induced neutropenia or a Non-FDA approved indication. In addition, the following criteria must be met:

Requests for treatment of chemotherapy induced neutropenia, approval requires:

- One of the following:
 - The patient's chemotherapy regimen has approximately $\geq 20\%$ risk of febrile neutropenia
 - The patient is at high-risk for neutropenic complications (e.g., age >65 , pre-existing neutropenia or tumor involvement in the bone marrow, infection, renal or liver impairment, or other serious co-morbidities)
- The requested medication is administered 24 to 72 hours after completion of chemotherapy
- The patient is not receiving concurrent chemotherapy and radiation therapy
- The requested medication is prescribed by or in consultation with a hematologist/oncologist or other specialist associated with the diagnosis or indication
- There is documentation (e.g., labs, medical records, special studies and/or physician attestation) of **BOTH** of the following:
 - The FDA approved indication
 - Absolute neutrophil count (ANC)

Requests for treatment of a Non-FDA approved indication, approval requires:

- The requested medication is prescribed by or in consultation with a hematologist/oncologist or other specialist associated with the diagnosis or indication
- There is medical literature or clinical studies from peer-reviewed journals with safety, efficacy, and dosing information for the intended use
- There is documentation (e.g., labs, medical records, special studies and/or physician attestation) of the patient's absolute neutrophil count (ANC)

INITIAL CRITERIA FOR ZARXIO:

The guideline named **GRANULOCYTE COLONY STIMULATING FACTORS (Zarxio)** requires that the request is for treatment of chemotherapy-induced neutropenia, treatment of neutropenia, or a Non-FDA approved indication. In addition, the following criteria must be met:

Requests for treatment of chemotherapy induced neutropenia, approval requires:

- One of the following:
 - The patient's chemotherapy regimen has approximately $\geq 20\%$ risk of febrile neutropenia
 - The patient is at high-risk for neutropenic complications (e.g., age >65 , pre-existing neutropenia or tumor involvement in the bone marrow, infection, renal or liver impairment, or other serious co-morbidities)

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

GRANULOCYTE COLONY STIMULATING FACTORS (MICHIGAN MEDICAID)

INITIAL CRITERIA FOR ZARXIO CONTINUED:

- The requested medication is administered 24 to 72 hours after completion of chemotherapy
- The patient is not receiving concurrent chemotherapy and radiation therapy
- The requested medication is prescribed by or in consultation with a hematologist/oncologist or other specialist associated with the diagnosis or indication
- There is documentation (e.g., labs, medical records, special studies and/or physician attestation) of **BOTH** of the following:
 - The FDA approved indication
 - Absolute neutrophil count (ANC)
- One of the following:
 - The patient has tried and failed or has a contraindication to Granix (TBO-Filgrastim)
 - The patient has issues related to geographic challenges and/or an inability to self-administer (Note: GCSF may be considered for coverage of the longer acting second line agents on a case by case basis.)

Requests for treatment of neutropenia, approval requires:

- One of the criteria has been met:
 - The patient has severe congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
 - The patient has drug induced neutropenia with immunosuppression and **ONE** of the following criteria has been met:
 - The patient has evidence of inadequate bone marrow reserve (e.g., recurrent fevers, splenomegaly, mucosal ulcers, or abdominal pain)
 - The patient is at high risk for the development of a serious bacterial infection (e.g., primarily severe neutropenia, indwelling venous catheters, or prior serious infection)
 - The patient has a documented bacterial infection (e.g., labs, medical records, special studies and/or physician attestation)
 - The request is for use for myeloid reconstitution after autologous or allogenic bone marrow transplant and the patient has a non-myeloid malignancy
 - The request is for use following reinfusion of peripheral blood stem cells (PBSCs)
- The requested medication is prescribed by or in consultation with a hematologist/oncologist or other specialist associated with the diagnosis or indication
- There is documentation (e.g., labs, medical records, special studies and/or physician attestation) of **BOTH** of the following:
 - The FDA approved indication
 - Absolute neutrophil count (ANC)

Requests for treatment of a Non-FDA approved indication, approval requires:

- The requested medication is prescribed by or in consultation with a hematologist/oncologist or other specialist associated with the diagnosis or indication
- There is medical literature or clinical studies from peer-reviewed journals with safety, efficacy, and dosing information for the intended use
- There is documentation (e.g., labs, medical records, special studies and/or physician attestation) of the patient's absolute neutrophil count (ANC)

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

GRANULOCYTE COLONY STIMULATING FACTORS (MICHIGAN MEDICAID)

INITIAL CRITERIA FOR NEUPOGEN:

The guideline named **GRANULOCYTE COLONY STIMULATING FACTORS (Neupogen)** requires that the request is for treatment of chemotherapy-induced neutropenia, treatment of neutropenia, or a Non-FDA approved indication. In addition, the following criteria must be met:

Requests for treatment of chemotherapy induced neutropenia, approval requires:

- One of the following:
 - The patient's chemotherapy regimen has approximately $\geq 20\%$ risk of febrile neutropenia
 - The patient is at high-risk for neutropenic complications (e.g., age >65 , pre-existing neutropenia or tumor involvement in the bone marrow, infection, renal or liver impairment, or other serious co-morbidities)
- The requested medication is administered 24 to 72 hours after completion of chemotherapy
- The patient is not receiving concurrent chemotherapy and radiation therapy
- The requested medication is prescribed by or in consultation with a hematologist/oncologist or other specialist associated with the diagnosis or indication
- The patient had a trial and failure or contraindication to Granix (TBO-Filgrastim) **AND** Zarxio (Filgrastim-SNDZ)
- There is documentation (e.g., labs, medical records, special studies and/or physician attestation) of **BOTH** of the following:
 - The FDA approved indication
 - Absolute neutrophil count (ANC)

Requests for treatment of neutropenia, approval requires:

- One of the following:
 - The patient has severe congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
 - The patient has drug induced neutropenia with immunosuppression and **ONE** of the following criteria:
 - The patient has evidence of inadequate bone marrow reserve (e.g., recurrent fevers, splenomegaly, mucosal ulcers, or abdominal pain)
 - The patient is at high risk for the development of a serious bacterial infection (e.g., primarily severe neutropenia, indwelling venous catheters, or prior serious infection)
 - The patient has a documented bacterial infection (e.g., labs, medical records, special studies and/or physician attestation)
 - The request is for use for myeloid reconstitution after autologous or allogenic bone marrow transplant and the patient has a non-myeloid malignancy
 - The request is for use following reinfusion of peripheral blood stem cells (PBSCs)
- The requested medication is prescribed by or in consultation with a hematologist/oncologist or other specialist associated with the diagnosis or indication
- There is documentation (e.g., labs, medical records, special studies and/or physician attestation) of **BOTH** of the following:
 - The FDA approved indication
 - Absolute neutrophil count (ANC)
- The patient has had a trial and failure or contraindication to Zarxio (Filgrastim-SNDZ)

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

GRANULOCYTE COLONY STIMULATING FACTORS (MICHIGAN MEDICAID)

INITIAL CRITERIA FOR NEUPOGEN CONTINUED:

Requests for treatment of a Non-FDA approved indication, approval requires:

- The requested medication is prescribed by or in consultation with a hematologist/oncologist or other specialist associated with the diagnosis or indication
- There is medical literature or clinical studies from peer-reviewed journals with safety, efficacy, and dosing information for the intended use
- There is documentation (e.g., labs, medical records, special studies and/or physician attestation) of the patient's absolute neutrophil count (ANC)

RENEWAL CRITERIA FOR GRANIX:

The guideline named **GRANULOCYTE COLONY STIMULATING FACTORS (Granix)** requires that the request is for treatment of chemotherapy-induced neutropenia or a Non-FDA approved indication. In addition, the following criteria must be met:

Requests for the treatment of chemotherapy-induced neutropenia, renewal requires:

- There is documentation (e.g., labs, medical record, special studies and/or physician attestation) of a recent ANC showing response to therapy

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Requests for a Non-FDA approved indication, renewal requires:

- There is documentation (e.g., labs, medical record, special studies and/or physician attestation) of a recent ANC

RENEWAL CRITERIA FOR NEUPOGEN OR ZARXIO:

The guideline named **GRANULOCYTE COLONY STIMULATING FACTORS (Neupogen, Zarxio)** requires the request is for treatment of chemotherapy-induced neutropenia, treatment of neutropenia, or a Non-FDA approved indication. In addition, the following criteria must be met:

Requests for the treatment of chemotherapy-induced neutropenia, renewal requires:

- There is documentation (e.g., labs, medical record, special studies and/or physician attestation) of a recent ANC showing response to therapy

Requests for treatment of neutropenia or a Non-FDA approved indication, renewal requires:

- There is documentation (e.g., labs, medical record, special studies and/or physician attestation) of a recent ANC

RATIONALE

To ensure appropriate use of Granix, Neupogen, Zarxio is consistent with FDA-approved indications and Michigan Medicaid requirements.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

GRANULOCYTE COLONY STIMULATING FACTORS (MICHIGAN MEDICAID)

FDA APPROVED INDICATIONS

ZARXIO

ZARXIO (FILGRASTIM-SNDZ) is indicated to:

- Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia with fever
- Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML)
- Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT)
- Mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
- Reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

NEUPOGEN

NEUPOGEN (FILGRASTIM) is indicated to:

- Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
- Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML)
- Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT)
- Mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
- Reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
- Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)

GRANIX

GRANIX (TBO-FILGRASTIM) is indicated in adult and pediatric patients 1 month and older for reduction in the duration of severe neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

GRANULOCYTE COLONY STIMULATING FACTORS (MICHIGAN MEDICAID)

Population	FDA labeling	Drug(s) Approved
Patients receiving radiation	Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)	Neupogen (filgrastim)
Non-myeloid cancer patients receiving myelosuppressive chemo	<i>For reduction in the duration of severe neutropenia</i> in adult and pediatric patients 1 month and older with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia	Granix (TBO-filgrastim)
	<i>Decrease the incidence of infection</i> , as manifested by neutropenia with fever, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever	Neupogen (filgrastim) Zarxio (filgrastim-sndz)
AML patients receiving induction or consolidation chemo	Reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML)	Neupogen (filgrastim) Zarxio (filgrastim-sndz)
Cancer patients undergoing BMT	Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation	Neupogen (filgrastim) Zarxio (filgrastim-sndz)
Undergoing peripheral blood progenitor cell collection	For the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis	Neupogen (filgrastim) Zarxio (filgrastim-sndz)
Severe chronic neutropenia	For chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia	Neupogen (filgrastim) Zarxio (filgrastim-sndz)

DOSAGE AND ADMINISTRATION

ZARXIO

- Patients with cancer receiving myelosuppressive chemotherapy or induction and/or consolidation chemotherapy for AML
 - Recommended starting dose is 5 mcg/kg/day subcutaneous injection, by short infusion (15 to 30 minutes), or by continuous intravenous infusion

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MCLAREN HEALTH PLAN MEDICAID PRIOR AUTHORIZATION GUIDELINES

GRANULOCYTE COLONY STIMULATING FACTORS (MICHIGAN MEDICAID)

- Patients with cancer undergoing bone marrow transplantation
 - 10 mcg/kg/day given as an intravenous infusion no longer than 24 hours
- Patients undergoing autologous peripheral blood progenitor cell collection and therapy
 - 10 mcg/kg/day subcutaneous injection administered for at least 4 days before first leukapheresis procedure and continue until last leukapheresis
- Patients with congenital neutropenia
 - Recommended starting dose is 6 mcg/kg subcutaneous injection twice daily
- Patients with cyclic or idiopathic neutropenia
 - Recommended starting dose is 5 mcg/kg subcutaneous injection daily

NEUPOGEN

- Patients with cancer receiving myelosuppressive chemotherapy or induction and/or consolidation chemotherapy for AML
 - Recommended starting dose is 5 mcg/kg/day subcutaneous injection, by short intravenous infusion (15 to 30 minutes), or by continuous intravenous infusion
- Patients with cancer undergoing bone marrow transplantation
 - 10 mcg/kg/day given as an intravenous infusion no longer than 24 hours
- Patients undergoing autologous peripheral blood progenitor cell collection and therapy
 - 10 mcg/kg/day subcutaneous injection administered for at least 4 days before first leukapheresis procedure and continue until last leukapheresis
- Patients with congenital neutropenia
 - Recommended starting dose is 6 mcg/kg subcutaneous injection twice daily
- Patients with cyclic or idiopathic neutropenia
 - Recommended starting dose is 5 mcg/kg subcutaneous injection daily
- Patients acutely exposed to myelosuppressive doses of radiation
 - Recommended starting dose is 10 mcg/kg subcutaneous injection daily, as soon as possible after suspected or confirmed exposure to radiation doses greater than 2 gray (Gy)

GRANIX

- Patients with cancer receiving myelosuppressive chemotherapy or induction and/or consolidation chemotherapy for AML
 - Recommended starting dose is 5 mcg/kg/day subcutaneous injection

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Contraindicated in patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors such as filgrastim or pegfilgrastim
- In addition, therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.
 - Warnings:
 - **Splenic rupture:** Rare cases of splenic rupture have been reported (may be fatal); in patients with upper abdominal pain, left upper quadrant pain, or shoulder tip pain, withhold treatment and evaluate for enlarged spleen or splenic rupture.^{1,2}
 - **Respiratory distress syndrome:** Acute respiratory distress syndrome (ARDS) has been reported. Evaluate patients who develop fever and lung infiltrates or respiratory distress for ARDS; discontinue in patients with ARDS.

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MCLAREN HEALTH PLAN MEDICAID PRIOR AUTHORIZATION GUIDELINES

GRANULOCYTE COLONY STIMULATING FACTORS (MICHIGAN MEDICAID)

- **Alveolar hemorrhage:** Reports of alveolar hemorrhage, manifested as pulmonary infiltrates and hemoptysis (requiring hospitalization), have occurred in healthy donors undergoing peripheral blood progenitor cell mobilization (unlabeled for use in healthy donors); hemoptysis resolved upon discontinuation.
- **Nephrotoxicity:** Based on findings of azotemia, hematuria (micro- and macro-scopic), proteinuria, and renal biopsy, glomerulonephritis has occurred in patients receiving filgrastim. Glomerulonephritis usually resolved after filgrastim dose reduction or discontinuation. If glomerulonephritis is suspected, evaluate for cause; if likely due to filgrastim, consider dose reduction or treatment interruption.
- **Sickle cell disorders:** May precipitate severe sickle cell crises, sometimes resulting in fatalities, in patients with sickle cell disorders (sickle cell trait or sickle cell disease); carefully evaluate potential risks and benefits. Discontinue in patients undergoing sickle cell crisis.
- **Capillary leak syndrome:** Capillary leak syndrome (CLS), characterized by hypotension, hypoalbuminemia, edema, and hemoconcentration, may occur in patients receiving human G-CSF. CLS episodes may vary in frequency and severity. If CLS develops, monitor closely and manage symptomatically (may require intensive care). CLS may be life-threatening if treatment is delayed.
- **Hematologic effects:** WBCs of 100,000/mm³ or more have been reported with filgrastim doses higher than 5 mcg/kg/day. When filgrastim products are used as an adjunct to myelosuppressive chemotherapy, discontinue when ANC exceeds 10,000/mm³ after the ANC nadir has occurred (to avoid potential excessive leukocytosis). Doses that increase the ANC beyond 10,000/mm³ may not result in additional clinical benefit. Monitor complete blood cell count (CBC) twice weekly during therapy. In patients receiving myelosuppressive chemotherapy, filgrastim discontinuation generally resulted in a 50% decrease in circulating neutrophils within 1 to 2 days, and a return to pretreatment levels in 1 to 7 days. When used for peripheral blood progenitor cell collection, discontinue filgrastim products if leukocytes greater than 100,000/mm³. Thrombocytopenia has also been reported with filgrastim products; monitor platelet counts.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION, CONTINUED

- **Severe chronic neutropenia:** Establish diagnosis of severe chronic neutropenia prior to initiation; use prior to appropriate diagnosis of severe chronic neutropenia may impair or delay proper evaluation and treatment for neutropenia due to conditions other than severe chronic neutropenia. Myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML) have been reported to occur in the natural history of congenital neutropenia (without cytokine therapy). Cytogenetic abnormalities and transformation to MDS and AML have been observed with filgrastim when used to manage severe chronic neutropenia, although the risk for MDS and AML appears to be in patients with congenital neutropenia. Abnormal cytogenetics and MDS are associated with the development of AML. The effects of continuing filgrastim products in patients who have developed abnormal cytogenetics or MDS are unknown; consider risk versus benefits of continuing treatment.¹
- **Cytotoxic chemotherapy:** Do not use filgrastim products in the period 24 hours before to 24 hours after administration of cytotoxic chemotherapy because of the potential sensitivity of rapidly dividing myeloid cells to cytotoxic chemotherapy. Transient increase in neutrophil count is seen 1 to 2 days after filgrastim initiation; however, for sustained neutrophil response, continue until post nadir ANC reaches 10,000/mm³.

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MCLAREN HEALTH PLAN MEDICAID PRIOR AUTHORIZATION GUIDELINES

GRANULOCYTE COLONY STIMULATING FACTORS (MICHIGAN MEDICAID)

- **Radiation therapy recipients:** Avoid concurrent radiation therapy with filgrastim products; safety and efficacy have not been established with patients receiving radiation therapy.
- **Tumor growth effects:** The G-CSF receptor through which filgrastim products act has been found on tumor cell lines. May potentially act as a growth factor for any tumor type (including myeloid malignancies and myelodysplasia). When used for stem cell mobilization, may release tumor cells from marrow that could be collected in leukapheresis product; potential effect of tumor cell reinfusion is unknown.
- **Cutaneous vasculitis:** Moderate or severe cutaneous vasculitis has been reported, generally occurring in patients with severe chronic neutropenia on long-term therapy. Withhold treatment if cutaneous vasculitis occurs; may be restarted with a dose reduction once symptoms resolve and the ANC has decreased.
- **Nuclear imaging:** Increased bone marrow hematopoietic activity due to colony stimulating factor (CSF) use has been associated with transient bone-imaging changes; interpret results accordingly.
- **Latex:** The packaging of some dosage forms may contain latex.
- **Polysorbate 80:** Some dosage forms may contain polysorbate 80 (also known as Tweens). Hypersensitivity reactions, usually a delayed reaction, have been reported following exposure to pharmaceutical products containing polysorbate 80 in certain individuals. Thrombocytopenia, ascites, pulmonary deterioration, and renal and hepatic failure have been reported in premature neonates after receiving parenteral products containing polysorbate 80. See manufacturer's labeling.
- **Appropriate use:** Filgrastim products should not be routinely used in the treatment of established neutropenic fever. CSFs may be considered in cancer patients with febrile neutropenia who are at high risk for infection-associated complications or who have prognostic factors indicative of a poor clinical outcome (eg, prolonged and severe neutropenia, older than 65 years, hypotension, pneumonia, sepsis syndrome, presence of invasive fungal infection, uncontrolled primary disease, hospitalization at the time of fever development). CSFs should not be routinely used for patients with neutropenia who are afebrile. Dose-dense regimens that require CSFs should only be used within the context of a clinical trial or if supported by convincing evidence.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION, CONTINUED

- **Hypersensitivity reactions:** Serious allergic reactions (including anaphylaxis) have been reported, usually with the initial exposure; may be managed symptomatically with administration of antihistamines, steroids, bronchodilators, and/or epinephrine. Allergic reactions may recur within days after the initial allergy management has been stopped. Do not administer filgrastim products to patients who experienced serious allergic reaction to filgrastim or pegfilgrastim. Permanently discontinue filgrastim products in patients with serious allergic reactions.

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MCLAREN HEALTH PLAN MEDICAID PRIOR AUTHORIZATION GUIDELINES

GRANULOCYTE COLONY STIMULATING FACTORS (MICHIGAN MEDICAID)

- **Pediatric:** CSF use in pediatric patients is typically directed by clinical pediatric protocols. The American Society of Clinical Oncology (ASCO) Recommendations for the Use of WBC Growth Factors Clinical Practice Guideline Update states that CSFs may be reasonable as primary prophylaxis in pediatric patients when chemotherapy regimens with a high likelihood of febrile neutropenia are employed. Likewise, secondary CSF prophylaxis should be limited to high-risk patients. In pediatric cancers in which dose-intense chemotherapy (with a survival benefit) is used, CSFs should be given to facilitate chemotherapy administration. CSFs should not be used in the pediatric population for non-relapsed acute lymphoblastic or myeloid leukemia when no infection is present.
- **Elderly:** The ASCO Recommendations for the Use of WBC Growth Factors Clinical Practice Guideline Update recommend that prophylactic CSFs be used in patients 65 years and older with diffuse aggressive lymphoma treated with curative chemotherapy (eg, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone), especially if patients have comorbid conditions.
- **Category C for pregnancy:** warn-precautions end pregnancy-lactation start
- **Drug interactions:**
 - Bleomycin toxicity and Cyclophosphamide may be increased when used with filgrastim, especially pulmonary toxicity
 - Topotecan toxicity may be enhanced with concomitant use of filgrastim
 - Use with caution with other drugs that may potentiate the release of neutrophils, e.g. lithium
- **Drug / Lab test interactions:**
 - May interfere with bone imaging studies; increased hematopoietic activity of the bone marrow may appear as transient positive bone imaging changes.

REFERENCES

- Zarxio [Prescribing Information]. Princeton, NJ. Sandoz Inc. December 2017.
- Granix [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals; July 2018.
- Neupogen [Prescribing Information]. Thousand Oaks, CA. Amgen Inc. June 2018.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_5228_28_7.pdf [Accessed October 1, 2018].

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P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

GLATIRAMER ACETATE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
GLATIRAMER ACETATE	GLATOPA GLATIRAMER ACETATE	12810		BRAND ≠ COPAXONE

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **GLATIRAMER ACETATE (generic Copaxone, Glatopa)** requires a diagnosis of a relapsing form of multiple sclerosis. In addition, the following criteria must be met.

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a neurologist
- There is documentation (e.g. Labs, Medical Record, and/or Special Studies) establishing the diagnosis of a relapsing form of multiple sclerosis

RENEWAL CRITERIA:

The guideline named **GLATIRAMER ACETATE (generic Copaxone, Glatopa)** requires a diagnosis of a relapsing form of multiple sclerosis. In addition, the following criterion must be met.

- There is certification/attestation from a neurologist that therapy has been effective (i.e., treatment has decreased relapses or diminished number of lesions on MRI)

RATIONALE

To ensure appropriate use of Copaxone consistent with FDA approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATION

Copaxone is indicated for the treatment of patients with relapsing forms of multiple sclerosis.

DOSAGE AND ADMINISTRATION

Copaxone is for subcutaneous use only. Do not administer intravenously. The dosing schedule depends on the product strength that is selected. The recommended doses are:

Copaxone 20 mg per mL: administer once per day

Copaxone 40 mg per mL: administer three times per week and at least 48 hours apart.

Copaxone 20 mg per mL and Copaxone 40 mg per mL are not interchangeable.

CONTRAINDICATION/EXCLUSION/DISCONTINUATION:

- **Systemic reactions:** immediate post injection systemic reactions occur in a substantial percentage of patients (approximately 16% [20 mg/mL] and approximately 2% [40 mg/mL] in studies); symptoms (anxiety, chest pain, constriction of the throat, dyspnea, flushing, palpitations, and urticaria) are usually self-limited and transient. These symptoms generally occur several months after initiation of treatment.
- Hypersensitivity to glatiramer acetate, mannitol, or any component of the formulation

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

GLATIRAMER ACETATE (MICHIGAN MEDICAID)

OTHER SPECIAL CONSIDERATIONS:

- **Chest pain:** May or may not occur with the immediate postinjection reaction; described as a transient pain usually resolving in a few minutes; often unassociated with other symptoms. Episodes usually begin 1 month or more after initiation of treatment.
- **Lipoatrophy:** May occur locally at injection site at various times after treatment (sometimes after several months) and may not resolve; to possibly minimize occurrence, advise patient to follow proper injection technique and rotate site with each injection. Skin necrosis has also been observed.
- **Immune response:** Although there has not been a systematic evaluation of glatiramer's potential to affect other immune functions, it may interfere with recognition of foreign antigens undermining the body's tumor surveillance and defense system against infection.
- **Antigenic:** Glatiramer acetate is antigenic and may possibly lead to the induction of untoward host responses. Glatiramer acetate–reactive antibodies (IgG subtype) form in most patients.
- **Drug-drug interactions:** Potentially significant interactions may exist, requiring dose or frequency adjustment, additional monitoring, and/or selection of alternative therapy.
- **Hypersensitivity reactions:** Anaphylactoid reactions (rare) have been reported.
- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REFERENCES

- Copaxone [Prescribing Information]. North Wales, PA. Teva Neuroscience, Inc.; August 2018.
- McLaren Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed August 20, 2018].

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P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

GLP 1 AGONISTS (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
LIRAGLUTIDE	VICTOZA		26189	
SEMIGLUTIDE	OZEMPIC		44163 44164	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **GLP 1 AGONISTS** requires a diagnosis of type 2 Diabetes Mellitus (DM) or that Victoza is being prescribed to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in an adult patient with type 2 Diabetes Mellitus (DM) and established cardiovascular disease. In addition, the following criteria must be met:

For patients with a diagnosis of type 2 diabetes mellitus, approval requires:

- The requested medication (Victoza or Ozempic) will be used as adjunct therapy to improve glycemic control,
- The patient is 18 years of age or older
- The patient has the following documentation (e.g. labs, medical records, special studies and/or physician attestation):
 - The patient has had a trial, failure or intolerance to at least **TWO** antidiabetic agents such as: metformin, sulfonylurea, thiazolidinedione (TZD), dipeptidyl peptidase-4 inhibitor (DDP-4 inhibitor), sodium-glucose co-transporter 2 (SGLT-2 inhibitor) **OR** insulin and has not achieved adequate glycemic control (HbA1c > 7% after 3 continuous months of receiving maximal daily doses) despite current treatment
 - Chart notes confirming all previous antidiabetic therapy; medications tried, dates of trial and response to therapy
 - Hemoglobin A1c ≤ 9%

For patients with a diagnosis of type 2 Diabetes Mellitus (DM) and established cardiovascular disease and Victoza is being prescribed to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke), no additional criteria is required for initial approval.

RENEWAL CRITERIA:

The guideline named **GLP 1 AGONISTS** requires a diagnosis of type 2 Diabetes Mellitus (DM) and that the requested medication is being used as adjunct therapy to improve glycemic control, OR Victoza is being prescribed to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in an adult patient with type 2 Diabetes Mellitus (DM) and established cardiovascular disease. In addition, the following criteria must be met:

- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) that the patient is tolerating and responding to treatment

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MCLAREN HEALTH PLAN MEDICAID PRIOR AUTHORIZATION GUIDELINES

GLP1 AGONIST (MICHIGAN MEDICAID)

RATIONALE

To ensure appropriate use of liraglutide (Victoza) and semaglutide (Ozempic) that is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

VICTOZA is indicated for the following:

- As adjunct therapy to diet and exercise in patients with type 2 Diabetes Mellitus (DM) to improve glycemic control
- To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 Diabetes Mellitus (DM) and established cardiovascular disease

Limitation of Use:

- VICTOZA and concurrent use of prandial insulin has not been studied.
- VICTOZA is not a substitute for insulin.
- VICTOZA should not be used in patients with Type 1 Diabetes Mellitus or for the treatment of diabetic ketoacidosis (it will not be effective in those settings).

FDA APPROVED INDICATIONS (CONTINUED)

OZEMPIC is indicated for the following:

- As adjunct therapy to diet and exercise in patients with type 2 Diabetes Mellitus (DM) to improve glycemic control

Limitation of Use:

- OZEMPIC is not recommended as a first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans.
- OZEMPIC has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- OZEMPIC is not a substitute for insulin. Ozempic is not indicated for use in patients with Type 1 Diabetes Mellitus or for the treatment of diabetic ketoacidosis (it will not be effective in those settings).

DOSAGE AND ADMINISTRATION

VICTOZA dosing recommendation is as follows:

- Victoza is injected subcutaneously once daily, at any time of the day and independent of meals.
- Victoza is initiated with a dose of 0.6mg per day for one week (this is to reduce gastrointestinal symptoms and is not effective for glycemic control). After one week of initiation of 0.6mg per day dosing, the dose can be increased to 1.2mg per day. If the 1.2mg dose does not produce acceptable glycemic control, the dose can be increased to 1.8mg per day.
- If a dose is missed, resume the once daily regimen as prescribed with the next scheduled dose (do not administer an extra dose or increase in dose to make up for the missed dose).
- If more than 3 days have lapsed since the last Victoza dose, reinstate Victoza at the 0.6mg per day dose to mitigate any gastrointestinal symptoms (upon reinstatement, titration is done at the discretion of the prescriber).

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

GLP1 AGONIST (MICHIGAN MEDICAID)

- When using Victoza concomitantly with an insulin secretagogue (e.g., sulfonylurea) or with insulin, consider reducing the dose of the insulin secretagogue or insulin to reduce the risk of hypoglycemia.

OZEMPIC dosing recommendation is as follows:

- Starting dose is 0.25 mg subcutaneously once weekly for 4 weeks, as this dose is intended for treatment initiation and is not effective for glycemic control.
- After 4 weeks, increase the dose to 0.5 mg once weekly.
- If after at least 4 weeks additional glycemic control is needed, the dosage may be increased to 1 mg once weekly. The maximum recommended dosage is 1 mg once weekly.
- Administer Ozempic once weekly, on the same day each week, at any time of day, with or without meals.
- If a dose is missed, administer within 5 days of missed dose. If more than 5 days have passed, skip the missed dose and administer the next dose on the regularly scheduled day.
- Inject Ozempic subcutaneously in the abdomen, thigh, or upper arm.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Not approved for convenience or if noncompliant with therapies
- HbA1c <7%
- Type 1 Diabetes Mellitus
- Hypersensitivity or contraindication to the use of Victoza or Ozempic
- Presence of medullary thyroid carcinoma (personal or family history)
- Presence of multiple endocrine neoplasia syndrome type 2
- Excluded if primarily being used for weight loss
- Boxed Warning: Thyroid C-cell tumor risk:
 - Victoza and Ozempic cause dose-dependent and treatment duration-dependent thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether GLP1 agonists cause thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, because the human relevance of Victoza-induced rodent thyroid C-cell tumors has not been determined.
 - Victoza and Ozempic are contraindicated in patients with a personal or family history of MTC and in patients with multiple endocrine neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Victoza and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Victoza.
- In addition, drug therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy

SPECIAL CONSIDERATIONS

- The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the benefits of Victoza outweigh the potential risk of medullary thyroid carcinoma and the risk of acute pancreatitis.
<http://www.victozapro.com/remis-program.aspx>

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

GLP1 AGONIST (MICHIGAN MEDICAID)

- Prescriber requirements: Prescribers are encouraged to review the Dear Healthcare Provider letter that provides safety information and prescribing recommendations for Victoza.
<http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM202063.pdf>.

REFERENCES

- Victoza [Prescribing Information]. Plainsboro, NJ: Novo Nordisk; January 2018.
- Ozempic [Prescribing Information] Plainsboro, NJ: Novo Nordisk; December 2017.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at:
https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

GROWTH HORMONE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
SOMATROPIN	NORDITROPIN FLEXPRO, NORDITROPIN NORDIFLEX		24145 24146 24147 25816	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **GROWTH HORMONE** requires a diagnosis of pediatric growth hormone deficiency (GHD), Turner Syndrome, Prader-Willi Syndrome, SHOX deficiency, Noonan Syndrome, chronic renal insufficiency (CRI) or small for gestational age (SGA) with failure to catch-up by 2 years of age, adult growth hormone deficiency (childhood-onset) due to idiopathic or known causes, adult-onset growth hormone deficiency due to known causes, HIV wasting or cachexia, short bowel syndrome or treatment of excess abdominal fat in HIV-infected patients with lipodystrophy. In addition, the following must be met:

For pediatric growth hormone deficiency (GHD), approval requires:

- The patient is less than 18 years of age
 - The requested medication is prescribed by or in consultation with a pediatric endocrinologist
 - The requested medication is not used for growth promotion in pediatric patients with epiphyseal closure
- [Note: linear growth can no longer occur i.e. bone age > 14 years old. The potential for achieving additional growth after Tanner 4-5 (full maturity) is small as this correlates with epiphyseal closure.]**
- Other factors contributing to growth failure have been ruled out, or are being treated (e.g. inadequate caloric intake/malnutrition/eating disorder, untreated hypothyroidism – patients need normal TSH, T4)
 - Recent (within the last 3 months) height more than 2 standard deviations (SD) below the mean (less than 3rd percentile) for normal children of the same age and sex
 - Recent (within the last 3 months) weight
 - Pretreatment growth velocity below normal for age and sex
 - There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of BOTH of the following:
 - Fasting Growth Hormone Stimulation test with arginine (ARG), clonidine, glucagon, insulin tolerance test (ITT) and/or levodopa
 - The patient has **ONE** of the following:
 - Peak Levels < 10 mcg/L from **TWO** different agents, if the cause of growth failure is unknown **OR**
 - **ONE** Peak level < 10 mcg/L, if the cause of growth failure is known and includes **ONE** of the following:
 - Structural or developmental abnormalities, i.e. anencephaly, pituitary aplasia **OR**
 - Genetic disorders, i.e. *PROP1* and *PIT1* mutations, septo-optic dysplasia **OR**
 - Acquired causes, i.e. craniopharyngeomas, cranial irradiation, brain surgery, head trauma, CNS infections
 - For neonates/infants, ONE of the following is met:
 - Random GH level < 20ng/mL (by RIA test)

MCLAREN HEALTH PLAN MEDICAID PRIOR AUTHORIZATION GUIDELINES

- Abnormal insulin-like growth factor-binding protein 3 (IGFBP-3) (in infants)
- Other causes have been ruled out or treated (i.e. hypothyroidism, metabolic disorders)

For Turner Syndrome, Prader-Willi Syndrome, SHOX deficiency, or Noonan Syndrome in pediatric patients, approval requires:

- The patient is less than 18 years of age
- The requested medication is prescribed by or in consultation with a pediatric endocrinologist
- The requested medication is not used for growth promotion in pediatric patients with epiphyseal closure
[Note: linear growth can no longer occur i.e. bone age > 14 years old. The potential for achieving additional growth after Tanner 4-5 (full maturity) is small as this correlates with epiphyseal closure.]
- Other factors contributing to growth failure have been ruled out, or are being treated (e.g. inadequate caloric intake/malnutrition/eating disorder, untreated hypothyroidism – patients need normal TSH, T4)
- Recent (within the last 3 months) height more than 2 standard deviations (SD) below the mean (less than 3rd percentile) for normal children of the same age and sex
- Recent (within the last 3 months) weight
- Pretreatment growth velocity below normal for age and sex
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) to support ONE of the requested diagnosis:
 - Turner Syndrome confirmed by karyotype studies, OR
 - Prader-Willi Syndrome confirmed by genetic testing

For chronic renal insufficiency (CRI) in pediatric patients, approval requires:

- The patient is less than 18 years of age
- The requested medication is prescribed by or in consultation with a pediatric endocrinologist or nephrologist
- The requested medication is not used for growth promotion in pediatric patients with epiphyseal closure
[Note: linear growth can no longer occur i.e. bone age > 14 years old. The potential for achieving additional growth after Tanner 4-5 (full maturity) is small as this correlates with epiphyseal closure.]
- Other factors contributing to growth failure have been ruled out, or are being treated (e.g. inadequate caloric intake/malnutrition/eating disorder, untreated hypothyroidism – patients need normal TSH, T4)
- Recent (within the last 3 months) height more than 2 standard deviations (SD) below the mean (less than 3rd percentile) for normal children of the same age and sex
- Recent (within the last 3 months) weight
- Pretreatment growth velocity below normal for age and sex
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of BOTH of the following:
 - The patient has not received a renal transplant
 - Existing metabolic abnormalities have been corrected (i.e. malnutrition, acidosis, secondary hyperparathyroidism and hyperphosphatemia – correct phosphorus to < 1.5 times the upper limit of age)

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

GROWTH HORMONE (MICHIGAN MEDICAID)

For patients small for gestational age (SGA) with failure to catch-up by 2 years of age, approval requires:

- The requested medication is prescribed by or in consultation with a pediatric endocrinologist
- The patient is at least 2 years of age
- The requested medication is not used for growth promotion in pediatric patients with epiphyseal closure
[Note: linear growth can no longer occur i.e. bone age > 14 years old. The potential for achieving additional growth after Tanner 4-5 (full maturity) is small as this correlates with epiphyseal closure.]
- Other factors contributing to growth failure have been ruled out, or are being treated (e.g. inadequate caloric intake/malnutrition/eating disorder, untreated hypothyroidism – patients need normal TSH, T4)
- Recent (within the last 3 months) height more than 2 standard deviations (SD) below the mean (less than 3rd percentile) for normal children of the same age and sex
- Recent (within the last 3 months) weight
- Pretreatment growth velocity below normal for age and sex
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of ONE of the following:
 - Birth length or weight < 3rd percentile for gestational age **OR**
 - Birth weight < 2500 grams at a gestational age of more than 37 weeks

For the diagnosis of adult growth hormone deficiency (childhood-onset) that is idiopathic, approval requires:

- The patient is 18 years of age or older
- The requested medication is prescribed by or in consultation with an endocrinologist
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of BOTH of the following:
 - The patient has idiopathic childhood-onset GHD
 - Verification that growth hormone was not taken for 1 to 3 months before ONE of the following results were obtained:
 - Baseline serum IGF-1
 - Growth hormone stimulation testing includes **ONE** of the following:
 - Insulin Tolerance Test (ITT): Peak less than or equal to 5 mcg/L
 - Glucagon [for patients who are unable to take ITT, alternative test if recombinant GHRH is unavailable or if ITT is contraindicated (seizures, CVD or cerebrovascular disease)]: Peak less than or equal to 3 mcg/L

[Note: Levodopa and clonidine tests are not recommended]

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

GROWTH HORMONE (MICHIGAN MEDICAID)

For the diagnosis of adult growth hormone deficiency (childhood-onset) that is due to a known cause, approval requires:

- The patient is 18 years of age or older
- The requested medication is prescribed by or in consultation with an endocrinologist
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of BOTH of the following:
 - The patient has childhood-onset GHD due to a known cause (e.g. structural lesions, genetic disorders, or acquired causes)
 - Baseline serum IGF-1

[Note: For conditions other than GHD, such as Turner Syndrome and small for gestational age, there is no proven benefit to continuing GH treatment into adulthood once final height is achieved]

For adult -onset growth hormone deficiency (GHD) acquired as an adult that is due to a known cause, approval requires:

- The patient is 18 years of age or older
- The requested medication is prescribed by or in consultation with an endocrinologist
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of ALL the following:
 - Diagnosis of GHD acquired as an adult due to known causes (e.g. surgery, cranial irradiation, panhypopituitarism)
 - Baseline serum IGF-1
 - Growth hormone stimulation testing includes **ONE** of the following:
 - Insulin Tolerance Test (ITT): Peak less than or equal to 5 mcg/L
 - Glucagon [for patients who are unable to take ITT, alternative test if recombinant GHRH is unavailable or if ITT is contraindicated (seizures, CVD or cerebrovascular disease)]: Peak less than or equal to 3 mcg/L

[Note: Levodopa and clonidine tests are not recommended. If GHD is due to traumatic brain injury and aneurysmal subarachnoid hemorrhage, GHD may be transient; therefore, GH stimulation testing should be performed at least 12 months after the event.]

For HIV wasting or cachexia in adult patients, approval requires:

- The patient is 18 years of age or older
- The requested medication is prescribed by or in consultation with an HIV specialist or endocrinologist
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of ALL the following:
 - Current height, weight and ideal body weight (IBW)
 - The patient had progressive weight loss below IBW over the last year which cannot be explained by a concurrent illness other than HIV infection
 - The patient has adequate caloric intake
 - The patient has had a trial and failure of megestrol AND dronabinol
 - The patient is on antiretroviral therapy

(Initial criteria continued on next page)

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

GROWTH HORMONE (MICHIGAN MEDICAID)

For short bowel syndrome in adult patients, approval requires:

- The patient is 18 years of age or older
- The requested medication is prescribed by or in consultation with an endocrinologist
- There documentation (e.g. labs, medical record, special studies and/or physician attestation) that the patient is receiving specialized nutrition (e.g. TPN or PPN)

For treatment of excess abdominal fat in adult HIV-infected patients with lipodystrophy, approval requires:

- The patient is between 18 and 65 years of age
- The requested medication is prescribed by or in consultation with an HIV specialist or endocrinologist
- There documentation (e.g. labs, medical record, special studies and/or physician attestation) of ALL the following:
 - The patient meets **ONE** of the following:
 - For Men: waist circumference greater than or equal to 95 cm (37.0") and waist-to-hip ratio greater than or equal to 0.94 **OR**
 - For Women: waist circumference greater than or equal to 94 cm (37.4") and waist-to-hip ratio greater than or equal to 0.88
 - The patient is on antiretroviral therapy
 - The patient is at risk for medical complications due to excess abdominal fat

No approval will be granted for the treatment of idiopathic short stature.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

GROWTH HORMONE (MICHIGAN MEDICAID)

RENEWAL CRITERIA:

The guideline named **GROWTH HORMONES** requires a diagnosis of growth hormone deficiency (GHD), Turner Syndrome, Prader-Willi Syndrome, SHOX deficiency, Noonan Syndrome, chronic renal insufficiency (CRI), small for gestational age (SGA) with failure to catch-up by 2 years of age, adult growth hormone deficiency (childhood-onset) due to idiopathic or known causes, adult-onset growth hormone deficiency due to known causes, HIV wasting or cachexia, or treatment of excess abdominal fat in HIV-infected patients with lipodystrophy. In addition, the following has to be met:

For pediatric patients with growth hormone deficiency (GHD), Turner Syndrome, Prader-Willi Syndrome, SHOX deficiency, Noonan Syndrome, or patients small for gestational age (SGA) with failure to catch-up by 2 years of age, approval requires:

- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) to support that final height has not been achieved
- No evidence of epiphyseal closure
- Growth velocity is > 5 cm/year on current dose or < 5 cm/year with intended dose increase

[Note: Growth velocity will typically decrease as final height is approached (growth velocity <2 cm/year).]

For the diagnosis of chronic renal insufficiency (CRI) prior to transplantation in pediatric patients, approval requires:

- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) to support that final height has not been achieved
- No evidence of epiphyseal closure
- The patient's growth velocity is > 5 cm/year on current dose or < 5 cm/year with intended dose increase

[Note: Growth velocity will typically decrease as final height is approached (growth velocity <2 cm/year).]

- The patient has not received more than three years of growth hormone treatment
- [Note: For CRI there is insufficient data regarding the benefit of treatment beyond 3 years.]**

For the diagnosis of adult growth hormone deficiency (childhood-onset) that is either idiopathic or due to a known cause, approval requires:

- Low IGF-1 and the GH dose is being increased **OR**
- IGF-1 level in a stable range

For adult-onset growth hormone deficiency (GHD) due to a known cause, approval requires:

- Low IGF-1 and the GH dose is being increased **OR**
- IGF-1 level in a stable range

(Renewal criteria continued on next page)

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

GROWTH HORMONE (MICHIGAN MEDICAID)

For HIV wasting or cachexia in adult patients, approval requires:

- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) to support to support response and continuation of therapy

For treatment of excess abdominal fat in adult HIV-infected patients with lipodystrophy, approval requires:

- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) to support response and continuation of therapy
- Decrease in waist circumference compared to baseline
- Documentation (e.g. labs, medical record, special studies and/or physician attestation) that IGF-1 and A1C is being monitored

No approval will be granted for the treatment of idiopathic short stature.

GROWTH HORMONE (MICHIGAN MEDICAID)

RATIONALE

To ensure appropriate use of Growth Hormones is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

	Ped growth hormone deficiency	Adult growth hormone deficiency	Small for gestational Age	Idiopathic short stature	Turner syndrome	Prader willi syndrome	Hiv-associated wasting	Short bowel syndrome	Noonan syndrome	Short stature homeobox-containing gene (shox) deficiency	Chronic kidney disease (chronic renal insufficiency)
Zorbtive								✓			
Serostim							✓				
Genotropin	✓	✓	✓	✓	✓	✓					
Norditropin	✓	✓	✓	✓	✓	✓			✓		
Humatrope	✓	✓	✓	✓	✓					✓	
Nutropin	✓	✓		✓	✓						✓
Omnitrope	✓	✓	✓	✓	✓	✓					
Saizen	✓	✓									
Zomacton	✓	✓	✓	✓	✓					✓	

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

GROWTH HORMONE (MICHIGAN MEDICAID)

DOSAGE AND ADMINISTRATION

Dosing of growth hormone products varies amongst the products and their indications. Treatment guidelines recommend that treatment be individualized. For pediatric patients, weight based-dosing is utilized, whereas in adult patients, either weight-base dosing or fixed-doses may be used.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Active malignancy
- Critical illness (e.g., after complications following open heart or abdominal surgery, multiple trauma, acute respiratory failure or similar conditions)
- Known hypersensitivity to growth hormone or to any of its excipients
- Intracranial hypertension
- Diabetic retinopathy, proliferative or pre-proliferative (*Note: Diabetes mellitus is not a contraindication, however GH therapy might impede the control of type 2 diabetes.*)
- Pregnancy or lactation: Pregnancy is not an absolute contraindication, but GH therapy during pregnancy is only recommended if clearly needed.
 - Category B: Genotropin, Omnitrope, Saizen, Serostim, and Zorbtive
 - Category C: Accretropin, Humatrope, Norditropin, Nutropin, Nutropin AQ, and Zomacton
- In addition, therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy
- No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy
- For the treatment of excess abdominal fat in adult HIV-infected patients with lipodystrophy: No disruption of the hypothalamic-pituitary axis (e.g. hypothalamic-pituitary-adrenal (HPA) suppression) due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, radiation therapy of the head or head trauma, active malignancy, known hypersensitivity to tesamorelin and/or mannitol, and pregnancy
- Children:
 - Not used in idiopathic short stature (not considered medically necessary)
 - Not used for growth promotion in pediatric patients with epiphyseal closure (linear growth can no longer occur. i.e., bone age > 14 years old). The potential for achieving additional growth after Tanner 4-5 (full maturity) is small as this correlates with epiphyseal closure.
 - Other factors contributing to growth failure have been ruled out, or are being treated (e.g., inadequate caloric intake/malnutrition/eating disorder, untreated hypothyroidism – patients need normal TSH, T4)

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

GROWTH HORMONE (MICHIGAN MEDICAID)

REFERENCES

- Genotropin [Prescribing Information]. New York, NY: Pharmacia & Upjohn Co.; December 2016.
- Humatrope [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; November 2017.
- Norditropin [Prescribing Information]. Plainsboro, NJ: Novo Nordisk; February 2018.
- Nutropin [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; January 2018.
- Omnitrope [Prescribing Information]. Princeton, NJ: Sandoz, Inc.; December 2016.
- Saizen [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; July 2018.
- Serostim [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; May 2018.
- Zorbtive [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; June 2017.
- Zomacton [Prescribing Information]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; July 2018.
- Egrifta [Prescribing Information]. Québec, Canada: Theratechnologies, Inc.; January 2018.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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Client Approval: 11/12/18

P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

IMIQUIMOD (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
IMIQUIMOD	ALDARA		54201	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **IMIQUIMOD (Aldara)** requires a diagnosis of actinic keratosis, superficial basal cell carcinoma, or external genital warts. In addition, the following criteria must be met.

For diagnosis of actinic keratosis or superficial basal cell carcinoma, approval requires:

- The patient is 12 years of age or older
- There is documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of an inadequate response or intolerance to office-based treatments, or have been considered and ruled out as options due to the nature/number of lesions or limited resources to provide such treatments

For diagnosis of external genital warts, approval requires:

- The patient is 12 years of age or older
- There is documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) that the patient has intolerance or contraindication (i.e. pregnancy) to a trial of podofilox solution

RENEWAL CRITERIA:

The guideline named **IMIQUIMOD (Aldara)** requires a diagnosis of actinic keratosis, superficial basal cell carcinoma, or external genital warts. In addition, the following criterion must be met.

- There is documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) that the patient has recurrence of active lesions and treatment with another course of therapy is required.

RATIONALE

To ensure appropriate use of Aldara consistent with FDA approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATION

Aldara cream is indicated for the following:

- Topical treatment of clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses on the face or scalp in immunocompetent adults
- Topical treatment of biopsy-confirmed, primary superficial basal cell carcinoma (sBCC) in immunocompetent adults, with a maximum tumor diameter of 2.0 cm, located on the trunk (excluding anogenital skin), neck, or extremities (excluding hands and feet), only when surgical methods are medically less appropriate and patient follow-up can be reasonably assured. The histological diagnosis of superficial basal cell carcinoma should be established prior to treatment, since safety and efficacy of ALDARA Cream have not been established for other types of basal cell carcinomas, including nodular and morpheaform (fibrosing or sclerosing) types
- Treatment of external genital and perianal warts/condyloma acuminata in patients 12 years or older

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MCLAREN HEALTH PLAN MEDICAID PRIOR AUTHORIZATION GUIDELINES

IMIQUIMOD (MICHIGAN MEDICAID)

Limitations of Use:

Aldara cream has been evaluated in children ages 2 to 12 years with molluscum contagiosum and these studies failed to demonstrate efficacy.

DOSAGE AND ADMINISTRATION

Aldara is not for oral, ophthalmic, or intravaginal use.

Actinic Keratosis: Aldara cream should be applied 2 times per week for a full 16 weeks to a defined treatment area on the face or scalp (but not both concurrently). The treatment area is defined as one contiguous area of approximately 25 cm² (e.g., 5 cm × 5 cm) on the face (e.g., forehead or one cheek) or on the scalp. Examples of 2 times per week application schedules are Monday and Thursday, or Tuesday and Friday. Aldara cream should be applied to the entire treatment area and rubbed in until the cream is no longer visible. No more than one packet of Aldara Cream should be applied to the contiguous treatment area at each application. Aldara cream should be applied prior to normal sleeping hours and left on the skin for approximately 8 hours, after which time the cream should be removed by washing the area with mild soap and water. The prescriber should demonstrate the proper application technique to maximize the benefit of Aldara cream therapy.

Superficial Basal Cell Carcinoma: Aldara cream should be applied 5 times per week for a full 6 weeks to a biopsy-confirmed sBCC. An example of a 5 times per week application schedule is to apply Aldara Cream, once per day, Monday through Friday. Aldara Cream should be applied prior to normal sleeping hours and left on the skin for approximately 8 hours, after which time the cream should be removed by washing the area with mild soap and water. The prescriber should demonstrate the proper application technique to maximize the benefit of Aldara cream therapy.

External Genital Warts: Aldara cream should be applied 3 times per week to external genital/perianal warts. Aldara cream treatment should continue until there is total clearance of the genital/perianal warts or for a maximum of 16 weeks. Examples of 3 times per week application schedules are: Monday, Wednesday, Friday or Tuesday, Thursday, Saturday. Aldara cream should be applied prior to normal sleeping hours and left on the skin for 6 –10 hours, after which time the cream should be removed by washing the area with mild soap and water. The prescriber should demonstrate the proper application technique to maximize the benefit of Aldara cream therapy

CONTRAINDICATION/EXCLUSION/DISCONTINUATION

- Cosmetic purposes
- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REFERENCES

- Aldara [Prescribing Information]. Bridgewater, NJ. Valeant Pharmaceuticals North America LLC; April 2018.
- McLaren Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed August 20, 2018].

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Page 106

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

INSULIN DEGLUDEC (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
INSULIN DEGLUDEC	TRESIBA, TRESIBA FLEXTOUCH U-100, TRESIBA FLEXTOUCH U-200		42785 35836 35837	

This drug requires a written request for NON-FORMULARY exception.

GUIDELINES FOR USE

INITIAL CRITERIA:

The non-formulary exception guideline named **INSULIN DEGLUDEC (TRESIBA)** requires a diagnosis of diabetes. In addition, the following criteria must be met:

- There is documentation (labs, medical record, special studies and/or physician attestation) for **ALL** of the following:
 - The patient has had a trial failure, or contraindication to ALL formulary agents: Basaglar Kwikpen

RENEWAL CRITERIA:

The non-formulary exception guideline named **INSULIN DEGLUDEC (TRESIBA)** requires a diagnosis of diabetes. In addition, there must be documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of ALL of the following:

- The patient currently meets ALL initial coverage criteria
- The patient is adherent to prescribed therapy
- Documentation of stabilization or improvement of symptoms.

FDA APPROVED INDICATIONS

Indicated to improve glycemic control in patients 1 year of age and older with diabetes mellitus.

DOSAGE AND ADMINISTRATION

In adults, inject subcutaneously once daily at any time of day. In pediatric patients inject subcutaneously once daily at the same time every day. Individualize dose based on type of diabetes, metabolic needs, blood glucose monitoring results and glycemic control goal.

REFERENCES

- Tresiba [Prescribing Information]. Bagsvaerd, Denmark, Novo Nordisk A/S; Dec 2018.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

INSULIN DETEMIR (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
INSULIN DETEMIR	LEVEMIR, LEVEMIR FLEXTOUCH, LEVEMIR FLEXPEN		25305 22836	

This drug requires a written request for NON-FORMULARY exception.

GUIDELINES FOR USE

INITIAL CRITERIA:

The non-formulary exception guideline named **INSULIN DETEMIR (Levemir)** requires a diagnosis of diabetes. In addition, the following criteria must be met:

- There is documentation (labs, medical record, special studies and/or physician attestation) for **ALL** of the following:
 - The patient has had a trial failure, or contraindication to ALL formulary agents: Basaglar Kwikpen

RENEWAL CRITERIA:

The non-formulary exception guideline named **INSULIN DETEMIR (Levemir)** requires a diagnosis of diabetes. In addition, there must be documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of ALL of the following:

- The patient currently meets ALL initial coverage criteria
- The patient is adherent to prescribed therapy
- Documentation of stabilization or improvement of symptoms.

FDA APPROVED INDICATIONS

Indicated to improve glycemic control in adults and children with diabetes mellitus.

DOSAGE AND ADMINISTRATION

Starting dose should be individualized based on the type of diabetes and whether the patient is insulin-naïve. Administer subcutaneously once daily or in divided doses twice daily. Once daily administration should be given with the evening meal or at bedtime.

REFERENCES

- Levemir [Prescribing Information]. Bagsvaerd, Denmark, Novo Nordisk A/S; Feb 2015.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

INSULIN GLARGINE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
INSULIN GLARGINE	LANTUS		13072	
INSULIN GLARGINE	LANTUS SOLOSTAR		98637	BRAND NAME = LANTUS SOLOSTAR
INSULIN GLARGINE	TOUJEO MAX SOLOSTAR, TOUJEO SOLOSTAR		44561 37988	

This drug requires a written request for NON-FORMULARY exception.

GUIDELINES FOR USE

INITIAL CRITERIA:

The non-formulary exception guideline named **INSULIN GLARGINE (Lantus & Toujeo)** requires a diagnosis of diabetes. In addition, the following criteria must be met:

- There is documentation (labs, medical record, special studies and/or physician attestation) for **ALL** of the following:
 - The patient has had a trial failure, or contraindication to ALL formulary agents: Basaglar Kwikpen

RENEWAL CRITERIA:

The non-formulary exception guideline named **INSULIN GLARGINE (Lantus & Toujeo)** requires a diagnosis of diabetes. In addition, there must be documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of ALL of the following:

- The patient currently meets ALL initial coverage criteria
- The patient is adherent to prescribed therapy
- Documentation of stabilization or improvement of symptoms.

FDA APPROVED INDICATIONS

Indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.

DOSAGE AND ADMINISTRATION

Individualize dosage based on metabolic needs, blood glucose monitoring, glycemic control, type of diabetes and prior insulin use. Should administer subcutaneously once daily at any time of day, but at the same time every day.

REFERENCES

- Lantus [Prescribing Information]. Bridgewater, NJ, Sanofi-aventis U.S. LLC; July 2015.
- Toujeo [Prescribing Information]. Bridgewater, NJ, Sanofi-aventis U.S. LLC; March 2018.

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P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

INSULIN REGULAR U500 (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
INSULIN REGULAR, HUMAN U-500	HUMULIN R U- 500		9633	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **INSULIN REGULAR U500 (Humulin R U-500)** requires that the request is to improve glycemic control in patients with diabetes mellitus or a non-FDA approved indication listed as a medically accepted indication as noted in one of the following compendia: American Hospital Formulary Drug Service (AHFS-DI), Micromedex DrugDex, or Clinical Pharmacology. In addition, the following criterion must be met as documented by labs, medical record, special studies and/or physician attestation:

- The patient requires more than 200 units of insulin per day

RENEWAL CRITERIA: The guideline named **INSULIN REGULAR U500 (Humulin R U-500)** requires that the request is to improve glycemic control in patients with diabetes mellitus or a non-FDA approved indication that is a medically accepted indication as noted in one of the following compendia: American Hospital Formulary Drug Service (AHFS-DI), Micromedex DrugDex, or Clinical Pharmacology. In addition, the following criterion must be met as documented by labs, medical record, special studies and/or physician attestation:

- The patient requires more than 200 units of insulin per day

RATIONALE

To ensure appropriate use of Humulin R U-500 is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

- Humulin R U 500 is a concentrated human insulin indicated to improve glycemic control in adults and children with diabetes mellitus requiring more than 200 units of insulin per day.
- Limitations of use: The safety and efficacy of Humulin R U-500 used in combination with other insulins has not been determined. The safety and efficacy of Humulin R U-500 delivered by continuous subcutaneous infusion has not been determined.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

INSULIN REGULAR U500 (MICHIGAN MEDICAID)

DOSAGE AND ADMINISTRATION

- The dosage of Humulin R is recommended to be individualized and adjusted based on metabolic needs, blood glucose monitoring results and glycemic control.
- Administer Humulin R U-500 subcutaneously two or three times daily 30 minutes before a meal. Do not mix Humulin R U-500 with other insulins.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- When above criteria are not met
- In addition, therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REFERENCES

- Humulin R U500 [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; July 2016.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at:
https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

INTERFERON BETA 1A (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
INTERFERON BETA 1A	AVONEX, AVONEX PEN	11253	20147 30222	
INTERFERON BETA- 1A/ALBUMIN	AVONEX ADMINISTRAT ION PACK,		23230	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **INTERFERON BETA 1A (Avonex)** requires a documented diagnosis of a relapsing form of multiple sclerosis (MS) (i.e., relapsing-remitting multiple sclerosis [RRMS], secondary-progressive multiple sclerosis [SPMS], or progressive-relapsing multiple sclerosis [PRMS]). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation a neurologist

RENEWAL CRITERIA: The guideline named **INTERFERON BETA 1A (Avonex)** requires a diagnosis of a relapsing form of multiple sclerosis (MS) (i.e., relapsing-remitting multiple sclerosis [RRMS], secondary-progressive multiple sclerosis [SPMS], or progressive-relapsing multiple sclerosis [PRMS]) **AND** a documentation of the following:

- Attestation from a neurologist that therapy has been effective (i.e. treatment has decreased relapses or diminished number of lesions on MRI)

RATIONALE

To ensure appropriate use of Avonex consistent with FDA approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATION

Avonex is indicated for the treatment of patients with relapsing forms of multiple sclerosis to slow the accumulation of physical disability and decrease the frequency of clinical exacerbations. Patients with multiple sclerosis in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis.

DOSAGE AND ADMINISTRATION

Avonex is for intramuscular use only. The recommended dose is 30 micrograms once a week. To reduce the incidence and severity of flu-like symptoms that may occur when initiating Avonex therapy at a dose of 30 micrograms, Avonex may be started at a dose of 7.5 micrograms and the dose may be increased by 7.5 micrograms each week for the next three weeks until the recommended dose of 30 micrograms is achieved.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

INTERFERON BETA 1A (MICHIGAN MEDICAID)

DOSAGE AND ADMINISTRATION (CONTINUED)

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- **Hypersensitivity reactions:** Allergic reactions, including anaphylaxis, have been reported. Some reactions may occur after prolonged use. Discontinue therapy if anaphylaxis or other allergic reactions occur
- Hypersensitivity to natural or recombinant interferon beta, human albumin (albumin containing formulations only), or any other component of the formulation
- **Autoimmune disorder development:** Consider discontinuing treatment. This can include bone marrow suppression with pancytopenia, leukopenia, and thrombocytopenia
- **Depression or other severe psychiatric symptoms:** Consider discontinuing treatment
- **Hepatotoxicity:**
 - **ALT more than 5 × ULN:** Temporarily discontinue therapy or consider dose reduction until ALT normalizes, then may consider retitration of dose
 - **Symptomatic (e.g., jaundice):** Discontinue immediately
 - **Leukopenia:** May require temporary discontinuation or dose reduction until resolution
 - **Albumin:** Some formulations contain albumin, which may carry a remote risk of transmitting Creutzfeldt-Jakob or other viral diseases. Interferon beta -1a formulations that contain albumin are contraindicated in albumin -sensitive patients
- **Injection-site reactions:** Severe injection-site reactions have occurred, including pain, erythema, edema, cellulitis, abscess, and necrosis. Necrosis may occur at single and multiple sites. Some reactions have occurred 2 or more years after initiation; reactions typically resolve with conservative treatment (antibiotics or surgical intervention may be required). Patient and/or caregiver competency in injection technique should be confirmed and periodically reevaluated
- **Cardiovascular disease:** Use with caution in patients with preexisting cardiovascular disease. Rare cases of new-onset cardiomyopathy and/or heart failure have been reported
- **Thyroid dysfunction:** Thyroid abnormalities may develop with use; may worsen preexisting thyroid conditions. Monitor thyroid function tests every 6 months or as clinically necessary
- **Thrombotic microangiopathy:** Cases of thrombotic microangiopathy manifesting as thrombotic thrombocytopenic purpura (TTP) or hemolytic uremic syndrome (HUS) (some fatal) have been reported. Some cases may occur after several years of therapy. Monitor for new-onset hypertension, thrombocytopenia, or impaired renal function; discontinuation of therapy and prompt treatment may be necessary if TTP/HUS are confirmed
- In addition, therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

OTHER SPECIAL CONSIDERATIONS

- Analgesics and/or antipyretics may help decrease flu-like symptoms on treatment days
- **Chronic progressive multiple sclerosis:** Safety and efficacy have not been established for this use
- **Latex:** The packaging (prefilled syringe tip cap) may contain latex

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

INTERFERON BETA 1A (MICHIGAN MEDICAID)

REFERENCES

- Avonex [Prescribing Information]. Cambridge, MA: Biogen Inc.; June 2017.
- McLaren Health Plan Common Formulary Prior Authorization Criteria. Available at:
https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_5228_28_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ISOTRETINOIN (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
ISOTRETINOIN	CLARAVIS	02476		ROUTE ≠ MISCELL.

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **ISOTRETINOIN (Claravis)** requires documented diagnosis of severe (multiple locations) recalcitrant nodular acne unresponsive to conventional therapy including conventional antibiotics, or a non-FDA approved indication and the request is for a medically accepted indication as noted in one of the following compendia: American Hospital Formulary Drug Service (AHFS-DI), Micromedex DrugDex, Clinical Pharmacology. **In addition, the following criteria must be met.**

- The patient is 12 years of age or older
- There is documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of ALL of the following:
 - Therapy is prescribed by or in consultation with a dermatologist
 - Current chart notes detailing the diagnosis, including laboratory tests as appropriate for diagnosis
 - Documentation of dose, dates of therapy, and clinical outcomes as appropriate
 - The patient has failed or is intolerant to at least 2 oral antibiotics (must have used consistently for 6 months)
 - The patient has failed or is intolerant to topical retinoid product (must have used consistently for 6 months)
 - The patient has failed or is intolerant to benzoyl peroxide wash (must have used consistently for 6 months)
 - The patient has failed or is intolerant to clindamycin and/or erythromycin topical therapy (must have used consistently for 6 months)
 - Negative pregnancy test
 - The patient has selected 2 forms of effective contraception to be used simultaneously
 - The patient meets requirements of the iPledge Program
- The requested medication will NOT be approved for the following:
 - The patient has any contraindications to the use of isotretinoin
 - The patient is not compliant with current therapy

RENEWAL CRITERIA:

The guideline named **ISOTRETINOIN (Claravis)** requires a documented diagnosis of severe (multiple locations) recalcitrant nodular acne, or a non-FDA approved, medically accepted indication as noted in an approved compendium. **In addition, the following criterion must be met.**

- There is documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of office visit every month with verified compliance and improvement or stability on drug

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MCLAREN HEALTH PLAN MEDICAID PRIOR AUTHORIZATION GUIDELINES

ISOTRETINOIN (MICHIGAN MEDICAID)

RATIONALE

To ensure appropriate use of Claravis consistent with FDA approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATION

Claravis (isotretinoin capsules) is indicated for the treatment of severe recalcitrant nodular acne. Nodules are inflammatory lesions with a diameter of 5 mm or greater. The nodules may become suppurative or hemorrhagic. "Severe," by definition, means "many" as opposed to "few or several" nodules. Because of significant adverse effects associated with its use, Claravis should be reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics. In addition, Claravis is indicated only for those female patients who are not pregnant, because Claravis can cause severe birth defects.

DOSAGE AND ADMINISTRATION

The recommended dosage range for Claravis is 0.5 to 1 mg/kg/day given in two divided doses with food for 15 to 20 weeks. In studies comparing 0.1, 0.5, and 1 mg/kg/day, it was found that all dosages provided initial clearing of disease, but there was a greater need for retreatment with the lower dosages. During treatment, the dose may be adjusted according to response of the disease and/or the appearance of clinical side effects – some of which may be dose related. Adult patients whose disease is very severe with scarring or is primarily manifested on the trunk may require dose adjustments up to 2 mg/kg/day, as tolerated. Failure to take Claravis with food will significantly decrease absorption. Before upward dose adjustments are made, the patients should be questioned about their compliance with food instructions.

The safety of once daily dosing with Claravis has not been established. Once daily dosing is not recommended.

If the total nodule count has been reduced by more than 70% prior to completing 15 to 20 weeks of treatment, the drug may be discontinued. After a period of 2 months or more off therapy, and if warranted by persistent or recurring severe nodular acne, a second course of therapy may be initiated. The optimal interval before retreatment has not been defined for patients who have not completed skeletal growth. Long-term use of Claravis, even in low doses, has not been studied, and is not recommended. It is important that Claravis be given at the recommended doses for no longer than the recommended duration. The effect of long-term use of Claravis on bone loss is unknown.

CONTRAINDICATION/EXCLUSION/DISCONTINUATION

- Patient is noncompliant with medical or pharmacologic therapy
- No demonstrable of improvement in clinical condition has occurred after initiation of drug therapy

REFERENCES

- Claravis [Prescribing Information]. North Wales, PA. Teva Pharmaceuticals USA, Inc.; May 2018.
- McLaren Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_5228_28_7.pdf [Accessed August 20, 2018].

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Page 116

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

LANTHANUM CARBONATE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
LANTHANUM CARBONATE	FOSRENOL CHEWABLE		26115 23813 26116	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **LANTHANUM CARBONATE (Fosrenol)** requires a diagnosis of chronic kidney disease requiring dialysis. In addition, the following criteria must be met:

- Therapy is prescribed by or in consultation with a nephrologist
- The patient is age 18 years or older
- There is documentation (e.g., labs, medical record, special studies and/or physician attestation) of **ALL** the following:
 - Hyperphosphatemia
 - The patient has had a trial and failure of calcium acetate (elevated phosphorus or calcium levels for consecutive measurements)
 - The patient has the inability to swallow tablets

RENEWAL CRITERIA:

The guideline named **LANTHANUM CARBONATE (Fosrenol)** requires the diagnosis of chronic kidney disease requiring dialysis and documentation (e.g., labs, medical record, special studies and/or physician attestation) of serum phosphorus levels for renewal.

RATIONALE

To ensure appropriate use of Fosrenol consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

Fosrenol is indicated to reduce serum phosphate in patients with end stage renal disease (ESRD).

DOSAGE AND ADMINISTRATION

The recommended initial total daily dose of Fosrenol is 1500mg in divided doses. Titrate every two to three weeks based on serum phosphate level.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Bowel obstruction.
- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

CONTINUED ON NEXT PAGE

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

LANTHANUM CARBONATE (MICHIGAN MEDICAID)

REFERENCES

- Fosrenol [Prescribing Information]. Lexington, MA: Shire US Inc.; February 2016.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_5228_28_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

LEVALBUTEROL SOLUTION (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
LEVALBUTEROL HCL	XOPENEX, XOPENEX CONCENTRATE	19858		EXCLUDE ≠ MISCELL.; POWDER NON-DRUGS

This drug requires a written request for NON-FORMULARY exception.

INITIAL CRITERIA:

The non-formulary exception guideline named **LEVALBUTEROL (Xopenex)** requires a diagnosis of asthma or bronchospasms associated with reversible obstructive airway disease. In addition, the following criteria must be met:

- There is documentation (labs, medical records, special studies and/or physician attestation) for trial, failure, or contraindication to **ALL** formulary agents: Ventolin HFA, albuterol HFA, or albuterol nebulizer solution.

RENEWAL CRITERIA:

The non-formulary exception guideline named **LEVALBUTEROL (Xopenex)** requires a diagnosis of asthma or bronchospasms associated with reversible obstructive airway disease. In addition, the following criteria must be met:

- The patient currently meets ALL initial coverage criteria
- The patient is adherent to prescribed therapy
- Documentation of stabilization or improvement of symptoms.

FDA APPROVED INDICATIONS

Indicated for the treatment or prevention of bronchospasm in patients 6 years of age and older with reversible obstructive airway disease.

DOSAGE AND ADMINISTRATION

The recommended dosage of Levalbuterol HCL Nebulizer solution is:

- Children 6-11 years old: 0.31mg by nebulization three times a day.
- Adults and Adolescents 12 years of age and older: 0.63mg by nebulization three times a day.
- Patients 12 years of age and older with more severe symptoms or who haven't responded to a dose of 0.63mg may benefit for a dosage of 1.25mg three times a day.

REFERENCES

- Xopenex Nebulizer Solution [Prescribing Information]. Marlborough, MA: Sunovion Pharmaceuticals, Inc.; March 2015.

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P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

L-GLUTAMINE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
L-GLUTAMINE	ENDARI		13365	BRAND=ENDARI

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **L-GLUTAMINE (Endari)** requires a diagnosis of sickle cell disease. In addition, the following criteria must be met as documented by labs, medical record, special studies and/or physician attestation):

- Therapy prescribed by or in consultation with hematologist
- The patient is 5 years of age or older
- The request is for an FDA approved dose
- The patient has had 2 or more crises in the last 12 months
- **ONE** of the following:
 - i. The patient had an inadequate response to an adherent, maximally tolerated dose of hydroxyurea for the past 180 days
 - ii. There is justification provided regarding intolerance or contraindication to the use of hydroxyurea

RENEWAL CRITERIA:

The guideline named **L-GLUTAMINE (Endari)** requires a diagnosis of sickle cell disease for renewal. In addition, the following criteria must be met:

- The patient continues on an FDA approved dose
- The patient has documentation (e.g., Labs, Medical Records, Special studies and/or Physician Attestation) of justification for continuation through positive outcomes in the past 6 months (e.g., reduction in the number of sickle cell crises).

RATIONALE

To ensure appropriate use of Endari consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

Endari is indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older.

DOSAGE AND ADMINISTRATION

Administer Endari orally, twice per day at the dose based on body weight according to Table 1.

Table 1. Recommended Dosing

Weight in kilograms	Weight in pounds	Per dose in grams	Per day in grams	Packets per dose	Packets per day
< 30	< 66	5	10	1	2
30 to 65	66 to 143	10	20	2	4
> 65	> 143	15	30	3	6

CONTINUED ON NEXT PAGE

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

L-GLUTAMINE (MICHIGAN MEDICAID)

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- No contraindications to report at this time.
- Warnings/Precautions: Use with caution in patients with hepatic and/or renal impairment. No specific dosage adjustments are documented.
- Safety has not been established in patients younger than 5 years old.
- No clinical benefit observed as measured by a reduction in the number of sickle cell crises or maintained improvement when compared history before initiation of Endari.

REFERENCES

- Endari [Prescribing Information]. Torrance, CA: Emmaus Medical, Inc.; June 2017.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

LINEZOLID (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
LINEZOLID	ZYVOX		26871 26870	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **LINEZOLID (Zyvox)** requires a diagnosis of pneumonia, skin and skin structure infection or vancomycin-resistant enterococcal infection, including cases with concurrent bacteremia.

In addition, the following must be met:

- The requested medication is prescribed by or in consultation with an Infectious Disease (ID) specialist that recommends Zyvox
- The requested medication will be administered orally
- The patient has documentation (e.g. labs, medical record, special studies and/or physician attestation) of **BOTH** the following:
 - The patient has culture and sensitivity that is susceptible to linezolid
 - The patient has a diagnosis supported by any applicable labs and/or tests as evidenced by the patient's medical record

RATIONALE

To ensure appropriate use of linezolid (Zyvox) is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

ZYVOX is indicated for the treatment of infections caused by susceptible strains of the designated microorganism in the specific conditions listed below:

Pneumonia

Nosocomial pneumonia caused by *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates) or *Streptococcus pneumoniae*

Community-acquired pneumonia caused by *Streptococcus pneumoniae*, including cases with concurrent bacteremia, or *Staphylococcus aureus* (methicillin-susceptible isolates only)

Skin and Skin Structure Infections

Complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis, caused by *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Streptococcus pyogenes*, or *Streptococcus agalactiae*.

Uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* (methicillin-susceptible isolates only) or *Streptococcus pyogenes*

Vancomycin-resistant *Enterococcus faecium* Infections

Vancomycin-resistant *Enterococcus faecium* infections, including cases with concurrent bacteremia

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

LINEZOLID (MICHIGAN MEDICAID)

Limitation of Use:

- ZYVOX has not been studied in the treatment of decubitus ulcers. Zyvox is not indicated for treatment of gram-negative infections (if a concomitant gram-negative pathogen is documented or suspected, initiate specific therapy immediately).

DOSAGE AND ADMINISTRATION

ZYVOX dosing recommendation is as follows:

Infection Type	Pediatric Patients (*Birth to 11 years of age)	Adults & Adolescents (12 years of age and older)	Recommended Treatment Days
Community acquired pneumonia, including concurrent bacteremia	10 mg/kg IV/PO every 8 hours	600 mg IV/PO every 12 hours	10 - 14
Complicated skin and skin structure			14 - 28
Vancomycin-resistant <i>Enterococcus faecium</i> (VRE), including concurrent bacteremia			
Uncomplicated skin and skin structure	< 5 years: 10 mg/kg PO every 8 hours	Adults: 400mg PO every 12 hours	10 - 14
	5-11 years: 10 mg/kg PO every 12 hours	Adolescents: 600mg PO every 12 hours	

Oral dosing can be using either Zyvox tablets of oral suspension.

*Neonates < 7 days: Most pre-term neonates less than 7 days of age (gestational age less than 34 weeks) have lower systemic linezolid clearance values and larger AUC values than many full-term neonates and older infants. These neonates should be initiated with a dosing regimen of 10 mg/kg every 12 hours. Consideration may be given to the use of 10 mg/kg every 8 hours regimen in neonates with a sub-optimal clinical response. All neonatal patients should receive 10 mg/kg every 8 hours by 7 days of life.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Hypersensitivity to linezolid or any component of the formulation
- Concurrent use or within 2 weeks of monoamine oxidase inhibitors (MAOIs)
- The patient is noncompliant with medical or pharmacologic therapy
- The patient demonstrates no clinically significant improvement in condition has occurred after initiation of drug therapy

SPECIAL CONSIDERATIONS

- The patient has a severe allergy to antibiotic to which the organism is susceptible **OR**
- The patient has failed treatment with antibiotic to which the organism is susceptible

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

LINEZOLID (MICHIGAN MEDICAID)

REFERENCES

- Zyvox [Prescribing Information]. New York, NY: Pharmacia and Upjohn Co.; July 2018.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_5228_28_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

LUBIPROSTONE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
LUBIPROSTONE	AMITIZA	33451		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **LUBIPROSTONE (Amitiza)** requires a documented diagnosis of chronic idiopathic constipation, irritable bowel syndrome with constipation, or opioid-induced constipation with chronic non-cancer pain. In addition, the following criteria must be met:

- The patient is 18 years of age or older
- Amitiza is prescribed by or in consultation with a gastroenterologist
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of **ALL** the following:
 - Dietary changes or dietary consultation, including the following:
 - Increase fluid intake
 - Increase dietary fiber intake
 - Increase mobility or exercise, if possible
 - The patient has had an inadequate response to standard therapy (less than 3 bowel movements over 7 days during the last 3 month period). Use of standard therapy laxatives must be in combination and documented in claims history. Standard therapy is defined as routine, scheduled use of 3 or more of the following:
 - Stool softeners
 - Stimulant laxatives
 - Bulk forming laxatives
 - Osmotic laxative
 - Lubricants
 - The patient has had a trial and failure for a minimum period of 14 days, contraindication, or intolerance to an osmotic laxative (e.g. Glycolax, miralax, PEG 3350)
 - The patient has had a trial and failure for a minimum period of 14 days, contraindication, or intolerance to lactulose for a minimum of 15mL daily

RENEWAL CRITERIA:

The guideline named **LUBIPROSTONE (Amitiza)** requires a diagnosis of chronic idiopathic constipation or irritable bowel syndrome with constipation or for opioid-induced constipation with chronic non-cancer pain. In addition, the following criteria must be met as documented by labs, medical record, special studies and/or physician attestation:

For chronic idiopathic constipation or irritable bowel syndrome with constipation, approval requires:

- The patient has a successful increase in bowel movements

For opioid-induced constipation with chronic non-cancer pain, approval requires:

- The patient has a successful increase in bowel movements
- Confirmation of no opioid dose escalation

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

LUBIPROSTONE (MICHIGAN MEDICAID)

RATIONALE

To ensure appropriate use of Amitiza is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

Amitiza is a chloride channel activator indicated for the treatment of:

- Chronic idiopathic constipation (CIC) in adults.
- Opioid-induced constipation (OIC) in adult patients with chronic, non- cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.
 - Limitations of Use: Effectiveness of Amitiza in the treatment of OIC in patients taking diphenylheptane opioids (e.g., methadone) has not been established.
- Irritable bowel syndrome with constipation (IBS-C) in women 18 years of age or older

DOSAGE AND ADMINISTRATION

- CIC and OIC: 24mcg twice daily
- IBS-C: 8 mcg twice daily

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Contraindicated in known or suspected mechanical gastrointestinal (GI) obstruction.
- Not approved for use in males with irritable bowel syndrome with constipation.
- Safety and effectiveness has not been establish in pediatric patients <6 years of age.
- Efficacy lubiprostone in the treatment of opioid-induced constipation in patients taking diphenylheptane opioids (e.g., methadone) has not been established.

OTHER SPECIAL CONSIDERATIONS

- Patient does not have a known or suspected mechanical gastrointestinal obstruction.
- Patient is not pregnant or breastfeeding.
- All requests must provide required documentation. No grandfathering.

REFERENCES

- Amitiza [Prescribing Information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; June 2018.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_5228_28_7.pdf [Accessed November 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

MECASERMIN (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
MECASERMIN	INCRELEX	33207		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **MECASERMIN (Increlex)** requires a diagnosis of severe primary IGF-1 deficiency or growth hormone (GH) gene deletion with neutralizing antibodies to GH. In addition, the following criteria must be met:

- The patient is between 2 and 18 years of age
- Increlex is prescribed by or in consultation with a pediatric endocrinologist

For patients with severe primary IGF-1 deficiency, approval also requires:

- Severe primary IGF-1 deficiency is caused by ONE of the following:
 - Mutation in the GH-receptor
 - Mutation in the post-GHR signaling pathway
 - IGF-1 gene defects
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of ALL of the following:
 - Current height measurement is less than the 3rd percentile for age and gender
 - IGF-1 level greater than or equal to 3 standard deviations below normal (based on lab reference range for age and gender)
 - Normal or elevated growth hormone (GH) levels
(Note: stimulation testing is not required when levels are normal or high)
 - Epiphyses (bone growth plates) must be confirmed as open for patients age 10 and older **(radiograph report required)**
 - Parental height **(height of each parent, if available, is required or explanation of why not available – such as child adopted, or one parent no longer involved and is unavailable for measurement)**
 - Clinically determined growth failure as defined by abnormally low growth rate velocity
 - Abnormal growth velocity is defined by the following:
 - The patient has a history of lower than normal growth velocity, as shown by growth charts spanning at least 6 months of time **AND**
 - The patient’s baseline height is less than the 3rd percentile or greater than 2 standard deviations (SD) below the mean for age and gender – **a measure of the degree of short stature**
 - Prescriber has submitted the patient’s height and weight measurements that must be logged in a table and plotted on standard CDC growth chart
 - Height and weight measurements must cover at least one-year time-span

For patients with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH, approval also requires:

- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of ALL of the following:
 - Current height measurement is less than the 3rd percentile for age and gender

(Initial criteria continued on next page)

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MCLAREN HEALTH PLAN MEDICAID PRIOR AUTHORIZATION GUIDELINES

MECASERMIN (MICHIGAN MEDICAID)

INITIAL CRITERIA CONTINUED:

- IGF-1 level greater than or equal to 3 standard deviations below normal (based on lab reference range for age and gender)
- The patient has stimulation testing for growth hormone (GH) levels
- Epiphyses (bone growth plates) are confirmed as open for patients age 10 and older **(radiograph report required)**
- Parental height **(height of each parent, if available, is required or explanation of why not available – such as child adopted, or one parent no longer involved and is unavailable for measurement)**
- Clinically determined growth failure as defined by abnormally low growth rate velocity
 - Abnormal growth velocity is defined by the following:
 - The patient has a history of lower than normal growth velocity, as shown by growth charts spanning at least 6 months of time **AND**
 - The patient's baseline height is less than the 3rd percentile or greater than 2 standard deviations (SD) below the mean for age and gender – **a measure of the degree of short stature**
 - Prescriber has submitted the patient's height and weight measurements that must be logged in a table and plotted on standard CDC growth chart
 - Height and weight measurements must cover at least one-year time-span*

**Exception: If a member is in puberty, bone age may be advancing secondary to sex hormone production. If previous growth data cannot be found to provide the "one-year" or longer time-span of data, then sexual maturity rating (Tanner Staging) and measurement of sex hormones may be submitted with only 6 months of growth data.*

RATIONALE

To ensure appropriate use of Increlex is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

INCRELEX (mecasermin [rDNA origin] injection) is indicated for the treatment of:

- Growth failure in children with severe primary IGF-1 deficiency, or
- Growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH

Mecasermin is contraindicated in patients with closed epiphyses (bone growth plates).

DOSAGE AND ADMINISTRATION

The recommended starting dose of INCRELEX is 0.04 to 0.08 mg/kg twice daily. If well tolerated for at least one week, the dose may be increased by 0.04 mg/kg per dose, to a maximum of 0.12 mg/kg twice daily.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

MECASERMIN (MICHIGAN MEDICAID)

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Closed epiphyses
- Active or suspected neoplasia
- Allergy to mecasecamin (IGF-1) or any of the inactive ingredients in mecasecamin
- Intravenous (IV) administration
- In addition, therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy
- No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy

SPECIAL CONSIDERATIONS

- Member is not receiving concurrent growth hormone therapy or pharmacologic doses of corticosteroids

REFERENCES

- Increlex [Prescribing Information]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; December 2017.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

MEDROXYPROGESTERONE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
MEDROXYPROGESTERONE ACETATE	DEPO-PROVERA SYRINGE		11254	IF APPROVED ENTER AUTH TO ALLOW A 90 DAY SUPPLY

This drug requires a written request for NON-FORMULARY exception.

GUIDELINES FOR USE

NON-FORMULARY CRITERIA:

The non-formulary exception guideline for **MEDROXYPROGESTERONE ACETATE 150MG/ML SYRINGE** requires that the patient:

- Have a documented reason as to why the Medroxyprogesterone Acetate 150mg/ml vial cannot be used.

FDA APPROVED INDICATIONS

Indicated for the prevention of pregnancy.

DOSAGE AND ADMINISTRATION

Recommended dose is 150mg administered by deep, IM injection in the gluteal or deltoid muscle.

REFERENCES

- Depo-Provera [Prescribing Information]. Kalamazoo, MI, Pharmacia & Upjohn Company; June 2002.

Created: 01/19

Effective: 02/01/19

Client approval: 01/29/19

P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

MEFLOQUINE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
MEFLOQUINE	LARIAM	04882		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **MEFLOQUINE (Lariam)** requires the request is for the treatment of acute malaria, or prevention or prophylaxis of malaria. In addition, the following must be met as documented by labs, medical record, special studies and/or physician attestation:

For the treatment of acute malaria, approval requires:

- The country or region where the patient will be traveling
- There are cultures and sensitivities to support malaria diagnosis

For the prevention or prophylaxis of malaria, approval requires:

- The request includes the country or region where the patient will be traveling
- The request includes the date and duration of travel
- The reason why mefloquine is requested instead of doxycycline

RATIONALE

To ensure appropriate use of Lariam is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

Lariam is indicated for the following:

- Treatment of mild to moderate acute malaria caused by mefloquine-susceptible strains of *P. falciparum* (both chloroquine-susceptible and resistant strains) or by *Plasmodium vivax*. There are insufficient clinical data to document the effect of mefloquine in malaria caused by *P. ovale* or *P. malariae*.
 - Note: Patients with acute *P. vivax* malaria, treated with Lariam, are at high risk of relapse because Lariam does not eliminate exoerythrocytic (hepatic phase) parasites. To avoid relapse, after initial treatment of the acute infection with Lariam, patients should subsequently be treated with an 8-aminoquinoline derivative (eg, primaquine).
- Prophylaxis of *P. falciparum* and *P. vivax* malaria infections, including prophylaxis of chloroquine-resistant strains of *P. falciparum*.

DOSAGE AND ADMINISTRATION

- The recommended dose for the treatment of mild to moderate acute malaria caused by *P. falciparum* (both chloroquine-susceptible and resistant strains) or by *Plasmodium vivax* is five tablets (1250mg) to be given as a single oral dose. If full-treatment course with Lariam does not lead to improvement within 48 to 72 hours, Lariam should not be used for re-treatment, but rather an alternative therapy should be used.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

MEFLOQUINE (MICHIGAN MEDICAID)

- The recommended dose for the prophylaxis of malaria is one 250mg tablet once weekly. Prophylactic drug administration should begin 1 week before arrival in an endemic area. Subsequent weekly doses should be taken regularly, always on the same day of each week, preferably after the main meal. To reduce the risk of malaria after leaving an endemic area, prophylaxis must be continued for 4 additional weeks to ensure suppressive blood levels.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REFERENCES

- Lariam [Prescribing Information]. Nutley, NJ: Roche Laboratories Inc.; April 2011.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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Client Approval: 10/26/18

P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

MOMETASONE/ FORMOTEROL (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
MOMETASONE/ FORMOTEROL	DULERA		28766 28767	

This drug requires a written request for NON-FORMULARY exception.

GUIDELINES FOR USE

INITIAL CRITERIA:

The non-formulary exception guideline for **MOMETASONE/ FORMOTEROL (DULERA)** requires a diagnosis of asthma. In addition, the following criteria must be met:

- The patient is 12 years of age or older
- There is documentation (labs, medical records, special studies and/or physician attestation) for **ALL** of the following:
 - The patient has had a trial, failure, or contraindication to all formulary agents: Fluticasone-Salmeterol (generic for Airduo Resplick), Pulmicort Flexhaler, and Qvar Redihaler; or have a documented reason why the patient would be unable to use the formulary agents.

RENEWAL CRITERIA:

The non-formulary exception guideline named **MOMETASONE/ FORMOTEROL (DULERA)** requires a diagnosis of asthma. In addition, there must be documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of ALL of the following:

- The patient currently meets ALL initial coverage criteria
- The patient is adherent to prescribed therapy
- Documentation of stabilization or improvement of symptoms.

FDA APPROVED INDICATIONS

Indicated for the treatment of asthma in patients 12 years of age and older. Dulera is not indicated for the relief of acute bronchospasm.

DOSAGE AND ADMINISTRATION

The recommended dosage of Dulera for the treatment of Asthma is two inhalations twice daily of the 100mcg/5ml or 200mcg/5ml inhaler.

REFERENCES

- Dulera [Prescribing Information]. Whitehouse Station, NJ: Merck & Co, Inc.; July 2018.

Created: 01/19

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Client Approval: 01/15/19

P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

NOVOLOG OR HUMALOG INSULIN (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
INSULIN ASPART	NOVOLOG CARTRIDGE, NOVOLOG VIAL, NOVOLOG FLEXPEN		92886 92326 92336	
INSULIN LISPRO	HUMALOG CARTRIDGE		5678	
INSULIN LISPRO	HUMALOG KWIK U-100		96719	BRAND NAME = HUMALOG KWIKPEN U-100
INSULIN LISPRO	HUMALOG JUNIOR KWIKPEN		43753	
INSULIN LISPRO	HUMALOG VIAL		5679	BRAND NAME = HUMALOG

This drug requires a written request for NON-FORMULARY exception.

GUIDELINES FOR USE

INITIAL CRITERIA:

The non-formulary exception guideline for **NOVOLOG OR HUMALOG INSULIN** requires a diagnosis of diabetes. In addition, the following criteria must be met:

- There is documentation (labs, medical record, special studies and/or physician attestation) for trial, failure, or contraindication to Admelog vials **OR**
- For Humalog only, the patient is on a continuous glucose monitoring pump

RENEWAL CRITERIA:

The non-formulary exception guideline named **NOVOLOG OR HUMALOG INSULIN** requires a diagnosis of diabetes. In addition, there must be documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of ALL of the following:

- The patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- For Humalog only, the patient's insulin continues to be delivered by an insulin pump

FDA APPROVED INDICATIONS

Indicated to improve glycemic control in adults and children with diabetes mellitus.

DOSAGE AND ADMINISTRATION

Individualize and adjust the dosage based on route of administration, the individual's metabolic needs, blood glucose monitoring results and glycemic control goal.

REFERENCES

- Novolog [Prescribing Information]. Bagsvaerd, Novo Nordisk A/S; Dec 2018.
- Humalog [Prescribing Information]. Indianapolis, IN, Lilly USA, LLC; Nov 2018.

Created: 01/19

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P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

NAPROXEN SUSPENSION (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
NAPROXEN SUSPENSION	NAPROSYN SUSPENSION		41670	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL/RENEWAL CRITERIA:

The guideline named **NAPROXEN SUSPENSION (Naprosyn suspension)** requires use for the relief of the signs and symptoms of Rheumatoid Arthritis, Osteoarthritis Ankylosing Spondylitis, or Juvenile Rheumatoid Arthritis (i.e., Polyarticular juvenile idiopathic arthritis). In addition, the following criteria must be met:

- The requested medication is prescribed by or in consultation with a rheumatologist
- The patient is 12 years of age or under
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of ONE of the following:
 - The patient has had a trial and failure of ibuprofen suspension
 - There is a clinical reason that ibuprofen suspension cannot be used

RATIONALE

To ensure appropriate use of Naprosyn suspension is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

Naprosyn suspension is a non-steroidal anti-inflammatory drug indicated for:

- The relief of the signs and symptoms of:
 - rheumatoid arthritis (RA)
 - osteoarthritis (OA)
 - ankylosing spondylitis (AS)
 - polyarticular juvenile idiopathic arthritis (PJIA)

DOSAGE AND ADMINISTRATION

Use the lowest effective dose for shortest duration consistent with individual patient treatment goals.

The recommended starting dose for RA, OA, or AS is 250mg to 500mg orally twice daily. The dose may be adjusted up or down depending on the clinical response. In patients who tolerate lower doses, the dose may be increased to naproxen 1500mg per day for up to 6 months.

The recommended total daily dose of naproxen for PJIA is approximately 10mg/kg given in two divided doses.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

NAPROXEN SUSPENSION (MICHIGAN MEDICAID)

REFERENCES

- Naprosyn suspension [Prescribing Information]. Alpharetta, GA: Canton Laboratories, LLC; March 2017.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

OCTREOTIDE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
OCTREOTIDE ACETATE	SANDOSTATIN		21765 21767 26541 26542	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **OCTREOTIDE (Sandostatin)** requires a diagnosis of acromegaly, metastatic vasoactive intestinal peptide tumors (VIPomas), use of chemotherapy or radiation, HIV/AIDS-induced diarrhea, metastatic carcinoid tumors, or carcinoid tumors. In addition, the following criteria must be met:

- The patient is 18 years of age or older
- The requested medication is prescribed by or in consultation with an endocrinologist
- The diagnosis is confirmed by labs, medical records, special studies and/or physician attestation

RENEWAL CRITERIA:

The guideline named **OCTREOTIDE (Sandostatin)** requires a diagnosis of acromegaly, metastatic vasoactive intestinal peptide tumors (VIPomas), use of chemotherapy or radiation, HIV/AIDS-induced diarrhea, metastatic carcinoid tumors, or carcinoid tumors. In addition, the following must be met:

For acromegaly, approval requires:

- The patient is 18 years of age or older
- The requested medication is prescribed by or in consultation with an endocrinologist
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of **ALL** the following:
 - Diagnosis of acromegaly
 - The patient has demonstrated a decrease or normalization of IGF-1 levels

For metastatic vasoactive intestinal peptide tumors (VIPomas), use of chemotherapy or radiation, HIV/AIDS-induced diarrhea, metastatic carcinoid tumors, or carcinoid tumors, approval requires:

- The patient is 18 years of age or older
- The requested medication is prescribed by or in consultation with an endocrinologist
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) to confirm the diagnosis

RATIONALE

To ensure appropriate use of Sandostatin is consistent with FDA-approved indications and Michigan Medicaid requirements.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

OCTREOTIDE (MICHIGAN MEDICAID)

FDA APPROVED INDICATIONS

SANDOSTATIN is indicated for:

Acromegaly

Octreotide Acetate Injection is indicated to reduce blood levels of growth hormone and IGF-I (somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses.

Carcinoid Tumors

Octreotide Acetate Injection is indicated for the symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease.

Vasoactive Intestinal Peptide Tumors

Octreotide Acetate Injection is indicated for the treatment of the profuse watery diarrhea associated with VIP-secreting tumors.

DOSAGE AND ADMINISTRATION

Acromegaly

Dosage may be initiated at 50 mcg three times daily. Beginning with this low dose may permit adaptation to adverse gastrointestinal effects for patients who will require higher doses. IGF-I (somatomedin C) levels every 2 weeks can be used to guide titration.

Carcinoid Tumors

The suggested daily dosage of Octreotide Acetate Injection during the first 2 weeks of therapy ranges from 100 to 600 mcg/day in 2 to 4 divided doses (mean daily dosage is 300 mcg).

Vasoactive Intestinal Peptide Tumors

Daily dosages of 200 to 300 mcg in 2 to 4 divided doses are recommended during the initial 2 weeks of therapy (range 150 to 750 mcg) to control symptoms of the disease. On an individual basis, dosage may be adjusted to achieve a therapeutic response, but usually doses above 450 mcg/day are not required.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- When above criteria are not met
- In addition, therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy
- No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REFERENCES

- Sandostatin [Prescribing Information]. Lake Zurich, IL: Fresenius Kabi USA, LLC; February 2018.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

OMEGA 3 ACID (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
OMEGA 3 ACID	LOVAZA	26793		BRAND NAME ≠ LOVAZA

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **OMEGA 3 ACID ETHYL ESTERS (Lovaza)** requires a diagnosis of hypertriglyceridemia (HTG). In addition, the following criteria must be met as documented by labs, medical record, special studies and/or physician attestation:

- The patient has had an inadequate response, intolerance, or contraindication to TWO formulary fibric acid derivatives: fenofibrate, fenofibric acid, or gemfibrozil
- The patient's triglyceride level is greater than or equal to 500mg/dL

RENEWAL CRITERIA:

The guideline named **OMEGA 3 ACID ETHYL ESTERS (Lovaza)** requires a diagnosis of hypertriglyceridemia (HTG) and documentation (e.g. labs, medical record, special studies and/or physician attestation) that the patient is responsive to Lovaza treatment.

RATIONALE

To ensure appropriate use of Lovaza is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

Lovaza is a combination of ethyl esters of omega 3 fatty acids, principally EPA and DHA, indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia (HTG).

Limitations of Use:

- The effect of Lovaza on the risk for pancreatitis has not been determined
- The effect of Lovaza on cardiovascular mortality and morbidity has not been determined

DOSAGE AND ADMINISTRATION

The daily dose of Lovaza is 4 grams per day taken as a single 4-gram dose (4 capsules) or as two 2-gram doses (2 capsules given twice daily).

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

OMEGA 3 ACID (MICHIGAN MEDICAID)

REFERENCES

- Lovaza [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline; September 2015.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ONCOLOGY AGENTS (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
ABIRATERONE ACET, SUBMICRONIZED	YONSA	44946		
ABIRATERONE ACETATE	ZYTIGA	37571		
APALUTAMIDE	ERLEADA	44773		
BEXAROTENE	TARGRETIN		92373	
BICALUTAMIDE	CASODEX	10143		
BUSULFAN	MYLERAN	03899		ROUTE = ORAL
CAPECITABINE	XELODA	18385		
CHLORAMBUCIL	LEUKERAN	03894		ROUTE ≠ MISCELL.
CYCLOPHOSPHAMIDE	CYCLOPHOSPHAMIDE		35317 35318	
ENASIDENIB MESYLATE	IDHIFA	44450		
ENCORAFENIB	BRAFTOVI	45039		
ENZALUTAMIDE	XTANDI	39580		
ESTRAMUSTINE PHOSPHATE SODIUM	EMCYT	03924		
ETOPOSIDE	VEPESID		7560	
EVEROLIMUS	AFINITOR		20784 20844 28783 31396	
EVEROLIMUS	AFINITOR DISPERZ		34589 34590 34592	
FLUTAMIDE	EULEXIN	03933		
INTERFERON ALFA-2B, RECOMB	INTRON A	04528		
IVOSIDENIB	TIBSOVO	45096		
LENALIDOMIDE	REVLIMID	33412		
LEUPROLIDE ACETATE	LUPRON		84597	
LOMUSTINE	GLEOSTINE		38431 38432 38433	
MELPHALAN	ALKERAN	07845		
MESNA	MESNEX		38953	
METHOTREXATE	XATMEP		43319	
MITOTANE	LYSODREN		38710	
NILUTAMIDE	NILANDRON	07876		
PANOBINOSTAT LACTATE	FARYDAK	41794		
POMALIDOMIDE	POMALYST	39996		
PROCARBAZINE HCL	MATULANE	03928		ROUTE ≠ MISCELL.
RUXOLITINIB PHOSPHATE	JAKAFI	38202		
SONIDEGIB PHOSPHATE	ODOMZO	42369		

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

Generic	Brand	HICL	GCN	Exception/Other
TEMOZOLOMIDE	TEMODAR	20355		ROUTE ≠ INTRAVEN.
THALIDOMIDE	THALOMID	11465		
THIOGUANINE	TABLOID	03911		ROUTE ≠ MISCELL.
TOPOTECAN HCL	HYCAMTIN		14254 14256	
TOREMIFENE CITRATE	FARESTON	11632		
TRETINOIN	VESANOID		48590	
TRIFLURIDINE/TIPIRACIL HCL	LONSURF	42544		
VISMODEGIB	ERIVEDGE	38455		
VORINOSTAT	ZOLINZA	34070		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **ONCOLOGY AGENTS** requires ALL of the following criteria to be met as documented by e.g. labs, medical record, special studies and/or physician attestation:

- The requested oncology agent is prescribed by or in consultation with an oncologist
- The patient has a diagnosis of an FDA-approved indication OR if the request is for a non-FDA-approved indication, the request must be for a “medically accepted indication” as noted in at least ONE of the following Compendia:
 - American Hospital Formulary Service Drug Information (AHFS-DI)
 - National Comprehensive Cancer Network (NCCN) Drugs and Biologic Compendium or NCCN Guidelines
 - Categories 1, 2a, and 2b will be accepted
 - Micromedex DrugDex
 - Clinical Pharmacology
- There is documentation of dose and dates of all previous therapy and the resulting outcomes
- There is documentation that the proper succession of the therapies has been tried and failed (i.e. intolerance, contraindication, or progression of disease)
- There are chart notes detailing the patient’s current clinical status
- Related lab work, test results, or clinical markers supporting the diagnosis and/or continuing treatment

RENEWAL CRITERIA:

The guideline named **ONCOLOGY AGENTS** requires that the following criteria are met as documented by e.g. labs, medical record, special studies and/or physician attestation:

- Current chart notes detailing response and compliance to therapy
- Documented clinically significant improvements in the disease state and stability on the medication

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

ONCOLOGY AGENTS (MICHIGAN MEDICAID)

RATIONALE

To ensure appropriate use of Formulary Oncology Agents are consistent with FDA-approved indications or Compendia and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

ONCOLOGY AGENTS per FDA-approved indications or Compendia

DOSAGE AND ADMINISTRATION

ONCOLOGY AGENTS per FDA-approved dosage and administration, or Compendia

Table 1: NCCN Categories of Evidence and Consensus.

<p>NCCN Categories of Evidence and Consensus</p> <p>Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.</p> <p>Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.</p> <p>Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.</p> <p>Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.</p> <p>All recommendations are category 2A unless otherwise noted.</p>
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CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION/ NOT APPROVED

- Hypersensitivity to the requested agent or any component of the formulation
- Member at risk through drug-drug interactions of contraindications noted in the package insert
- Patient is noncompliant with medical or pharmacologic therapy
- No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy
- Patient has any contraindications to the use of any requested ingredients
- Request is for experimental/investigational use
- Member is enrolled in a clinical trial

REFERENCES

- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].
- National Comprehensive Cancer Network® (NCCN), “Clinical Practice Guidelines in Oncology™”: Available at <http://www.nccn.org>

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

OVERACTIVE BLADDER (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
SOLIFENACIN SUCCINATE	VESICARE		23276 23277	
FESOTERODINE FUMARATE	TOVIAZ		99711 99712	
DARIFENACIN HYDROBROMIDE	ENABLEX		24043 24044	
MIRABEGRON	MYRBETRIQ		32766 32767	

This drug requires a written request for NON-FORMULARY exception.

GUIDELINES FOR USE

INITIAL CRITERIA:

The non-formulary exception guideline named **OVERACTIVE BLADDER (SOLFENACIN, FESOTERODINE, DARIFENACIN, OR MIRABEGRON)** requires a diagnosis of overactive bladder with urge urinary incontinence. In addition, the following criteria must be met:

- The patient is 18 years of age or older
- There is documentation (labs, medical record, special studies and/or claims history) for **ALL** of the following:
 - The patient has had a trial, failure, or contraindication to **ALL** of the following: oxybutynin (Ditropan), oxybutynin ER (Ditropan XL), tolterodine (Detrol), tolterodine ER (Detrol LA), **AND** trospium (Sanctura).

RENEWAL CRITERIA:

The non-formulary exception guideline named **OVERACTIVE BLADDER (SOLFENACIN, FESOTERODINE, DARIFENACIN, OR MIRABEGRON)** requires a diagnosis of overactive bladder with urge urinary incontinence. In addition, there must be documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of ALL of the following:

- The patient currently meets ALL initial coverage criteria
- The patient is adherent to prescribed therapy
- Documentation of stabilization or improvement of symptoms.

FDA APPROVED INDICATIONS

Indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.

DOSAGE AND ADMINISTRATION

Vesicare: Recommended dose of Vesicare is 5mg by mouth once daily. If the 5mg dose is well tolerated, the dose may be increased to 10mg once daily.

Toviaz: Recommended dose of Toviaz is 4mg by mouth once daily. If the 4mg dose is well tolerated, the dose may be increased to 8mg once daily.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

Enablex: Recommended starting dose of Enablex extended-release tablets is 7.5mg by mouth once daily. Based upon individual response, the dose may be increase to 15mg once daily, as early as two weeks after starting therapy.

Myrbetriq: Recommended starting dose is 25mg by mouth once daily, alone or in combination with solifenacin succinate 5mg, once daily. Based on individual efficacy and tolerability, may increase dose to 50mg once daily, alone or in combination with solifenacin succinate 5mg, once daily.

REFERENCES

- Vesicare [Prescribing Information]. Northbrook, IL, Astellas Pharma US, Inc; Feb 2016.
- Toviaz [Prescribing Information]. Wilmington, DE, AstraZeneca Pharmaceuticals LP; Jan 2018.
- Enablex [Prescribing Information]. Fajardo, Puerto Rico, Novartis Pharma Stein AG; March 2012.
- Myrbetriq [Prescribing Information]. Northbrook, IL, Astellas Pharma US, Inc; April 2018.

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P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PULMONARY ARTERIAL HTN – AMBRISENTAN (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
AMBRISENTAN	LETAIRIS	34849		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **PULMONARY ARTERIAL HTN – AMBRISENTAN (Letairis)** requires a diagnosis of primary pulmonary hypertension or secondary pulmonary hypertension due to scleroderma, sclerosis or autoimmune disease. In addition, the following criteria must be met:

- The patient is 18 years of age or older
- Letairis is prescribed by or in consultation with a pulmonologist or cardiologist
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) for ALL of the following:
 - The diagnosis is defined as WHO Group I with NYHA functional class II or III
 - The patient has received adequate treatment trial with anticoagulants +/- diuretics +/- digoxin
 - The patient has acute vasoreactivity testing result:
 - For patients with positive testing result – a trial and failure with calcium channel blocker therapy, unless it is contraindicated, such as those with right heart failure or hemodynamic instability **OR**
 - For patients with negative testing result, calcium channel blocker is not indicated

RENEWAL CRITERIA:

The guideline named **PULMONARY ARTERIAL HTN – AMBRISENTAN (Letairis)** requires a diagnosis of primary pulmonary hypertension or secondary pulmonary hypertension due to scleroderma, sclerosis or autoimmune disease. In addition, ONE of the following criteria must be met with documentation (e.g. labs, medical record, special studies and/or physician attestation):

- The patient has stabilization or improvement in functional status (NYHA functional class) **OR**
- Improvement in PAP or other measures of pulmonary hypertension

RATIONALE

To ensure appropriate use of Letairis is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

LETAIRIS is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to:

- Improve exercise ability and delay clinical worsening
- In combination with tadalafil to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability

DOSAGE AND ADMINISTRATION

LETAIRIS initial dosing recommendation in adult patients starts at 5 mg orally once daily, with or without tadalafil 20mg once daily. At 4-week intervals, either the dose of Letairis or tadalafil can be increased, as needed and tolerated, to Letairis 10mg or tadalafil 40mg.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PULMONARY ARTERIAL HTN – AMBRISENTAN (MICHIGAN MEDICAID)

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- **Boxed Warning: Pregnancy:** Do not administer ambrisentan to a pregnant woman because it may cause fetal harm. Ambrisentan is very likely to produce serious birth defects if used by pregnant women because this effect has been seen consistently when it is administered to animals. Therefore, pregnancy must be excluded before the initiation of treatment. Females of reproductive potential must use acceptable methods of contraception during treatment and for 1 month after treatment. Obtain monthly pregnancy tests during treatment and 1 month after discontinuation.
- Hypersensitivity to any product
- Idiopathic pulmonary fibrosis, including idiopathic pulmonary fibrosis patients with pulmonary hypertension (WHO group 3)
- In addition, drug therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Appendix A: WHO Classification of Pulmonary Hypertension

The World Health Organization divides pulmonary hypertension (PH) into five groups. These groups are organized based on the cause of the condition. Note that group 1 is called pulmonary arterial hypertension (PAH) and groups 2 through 5 are called pulmonary hypertension. However, together all groups are called pulmonary hypertension.

Group 1 Pulmonary Arterial Hypertension (PAH) includes:

- Idiopathic - PAH that has no known cause.
- Heritable - PAH that is inherited (passed from parents to children through genes).
- Drug and Toxin induced - PAH that is caused by drugs or toxins, such as street drugs and certain diet medicines.
- PAH that is caused by conditions such as:
 - Connective tissue diseases
 - HIV infection
 - Liver disease
 - Congenital heart disease
 - Sickle cell disease
 - Schistosomiasis
- PAH that is caused by conditions that affect the veins and small blood vessels of the lungs.

Group 2 Pulmonary Hypertension with Left Heart Disease

- Conditions that affect the left side of the heart, such as:
 - Mitral valve disease
 - Long term high blood pressure

Group 3 Pulmonary Hypertension associated with Lung Diseases such as:

- Chronic obstructive pulmonary disease (COPD)
- Interstitial lung diseases
- Pulmonary Hypertension associated with sleep-related breathing disorders, such as obstructive sleep apnea, Cheyne-Stokes respiration (CSR) and central sleep apnea (CSA)

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PULMONARY ARTERIAL HTN – AMBRISENTAN (MICHIGAN MEDICAID)

Appendix A (continued)

Group 4 Chronic Thromboembolic Pulmonary Hypertension (CTEPH) includes:

- PH caused by blood clots in the lungs
- PH caused by blood clotting disorders

Group 5 Pulmonary Hypertension caused by various other diseases or conditions:

- Blood disorders, such as:
 - Polycythemia vera
 - Essential thrombocythemia
- Systemic disorders, such as:
 - Sarcoidosis
 - Vasculitis
- Metabolic disorders, such as:
 - Thyroid disease
 - Glycogen storage disease
- Other conditions, such as:
 - Tumors that press on the pulmonary arteries
 - Kidney disease

Appendix B: New York Heart Association Functional Classification

- **Class I:** Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.
- **Class II:** Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.
- **Class III:** Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.
- **Class IV:** Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

REFERENCES

- Letairis [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; October 2015.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].
- The Criteria Committee of the New York Heart Association. *Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels*. 9th ed. Boston, Mass: Little, Brown & Co; 1994: 253-256.
- "Types of Pulmonary Hypertension" (2011, August 2). Retrieved from <http://www.nhlbi.nih.gov/health/health-topics/topics/pah/>

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P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PULMONARY ARTERIAL HTN – BOSENTAN (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
BOSENTAN	TRACLEER	22990		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **BOSENTAN (Tracleer)** requires a diagnosis of primary pulmonary hypertension or secondary pulmonary hypertension due to scleroderma, sclerosis or autoimmune disease. In addition, the following criteria must be met:

- Tracleer is prescribed by or in consultation with a pulmonologist or cardiologist
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of ALL of the following:
 - WHO Group I
 - NYHA functional class II, III or IV
 - Patient has received adequate treatment trial with anticoagulants +/- diuretics +/- digoxin
 - Acute vasoreactivity testing result:
 - For patients with a positive testing result: patient has a contraindication or had trial and failure with calcium channel blocker therapy OR
 - For patients with a negative testing result: calcium channel blocker therapy is not indicated

RENEWAL CRITERIA:

The guideline named **BOSENTAN (Tracleer)** requires a diagnosis of primary pulmonary hypertension or secondary pulmonary hypertension due to scleroderma, sclerosis or autoimmune disease. In addition, ONE of the following criteria must be met as documented by labs, medical record, special studies and/or physician attestation:

- The patient has stabilization or improvement in functional status (NYHA functional class) OR
- The patient has improvement in PAP or other measures of pulmonary hypertension

RATIONALE

To ensure appropriate use of Tracleer is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

TRACLEER is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) in:

- Adults to improve exercise ability and to decrease clinical worsening
- Pediatric patients aged 3 years and older with idiopathic or congenital PAH to improve pulmonary vascular resistance (PVR), which is expected to result in an improvement in exercise ability

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PULMONARY ARTERIAL HTN – BOSENTAN (MICHIGAN MEDICAID)

DOSAGE AND ADMINISTRATION

TRACLEER dosing recommendation is as follows:

Age and Weight (kg)	Initial 4 Weeks	Maintenance (after 4 weeks)
Patient > 12 years of age and > 40kg	62.5mg twice daily	125mg twice daily
Patients > 12 years of age and < 40kg	62.5mg twice daily	
Patients ≤ 12 years of age and:		
≥ 4 – 8 kg	16mg twice daily	
> 8 – 16kg	32mg twice daily	
>16 – 24kg	48mg twice daily	
>24 – 40kg	64mg twice daily	

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- **Boxed Warning: Pregnancy-** Do not administer ambrisentan to a pregnant woman because it may cause fetal harm. Ambrisentan is very likely to produce serious birth defects if used by pregnant women because this effect has been seen consistently when it is administered to animals. Therefore, pregnancy must be excluded before the initiation of treatment. Females of reproductive potential must use acceptable methods of contraception during treatment and for 1 month after treatment. Obtain monthly pregnancy tests during treatment and 1 month after discontinuation.
- Hypersensitivity to any product
- Drug interaction specific to Bosentan: concomitant use with cyclosporine A or glyburide
- In addition, drug therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Appendix A: WHO Classification of Pulmonary Hypertension

The World Health Organization divides pulmonary hypertension (PH) into five groups. These groups are organized based on the cause of the condition. Note that group 1 is called pulmonary arterial hypertension (PAH) and groups 2 through 5 are called pulmonary hypertension. However, together all groups are called pulmonary hypertension.

Group 1 Pulmonary Arterial Hypertension (PAH) includes:

- Idiopathic - PAH that has no known cause.
- Heritable - PAH that is inherited (passed from parents to children through genes).
- Drug and Toxin induced - PAH that is caused by drugs or toxins, such as street drugs and certain diet medicines.
- PAH that is caused by conditions such as:
 - Connective tissue diseases
 - HIV infection
 - Liver disease
 - Congenital heart disease
 - Sickle cell disease
 - Schistosomiasis
- PAH that is caused by conditions that affect the veins and small blood vessels of the lungs.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PULMONARY ARTERIAL HTN – BOSENTAN (MICHIGAN MEDICAID)

Group 2 Pulmonary Hypertension with Left Heart Disease

- Conditions that affect the left side of the heart, such as:
 - Mitral valve disease
 - Long term high blood pressure

Group 3 Pulmonary Hypertension associate with Lung Diseases such as:

- Chronic obstructive pulmonary disease (COPD)
- Interstitial lung diseases
- Pulmonary Hypertension associated with sleep-related breathing disorders, such as obstructive sleep apnea, Cheyne-Stokes respiration (CSR) and central sleep apnea (CSA)

Group 4 Chronic Thromboembolic Pulmonary Hypertension (CTEPH) includes:

- PH caused by blood clots in the lungs
- PH caused by blood clotting disorders

Appendix A (continued)

Group 5 Pulmonary Hypertension caused by various other diseases or conditions:

- Blood disorders, such as:
 - Polycythemia vera
 - Essential thrombocythemia
- Systemic disorders, such as:
 - Sarcoidosis
 - Vasculitis
- Metabolic disorders, such as:
 - Thyroid disease
 - Glycogen storage disease
- Other conditions, such as:
 - Tumors that press on the pulmonary arteries
 - Kidney disease

Appendix B: New York Heart Association Functional Classification

- **Class I:** Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.
- **Class II:** Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.
- **Class III:** Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.
- **Class IV:** Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PULMONARY ARTERIAL HTN – BOSENTAN (MICHIGAN MEDICAID)

REFERENCES

- Tracleer [Prescribing Information]. South San Francisco, CA: Actelion Pharmaceutical US, Inc.; December 2017.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].
- The Criteria Committee of the New York Heart Association. *Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels*. 9th ed. Boston, Mass: Little, Brown & Co; 1994: 253-256.
- “Types of Pulmonary Hypertension” (2011, August 2). Retrieved from <http://www.nhlbi.nih.gov/health/health-topics/topics/pah/>

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PULMONARY ARTERIAL HTN - RIOCIQUAT (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
RIOCIQUAT	ADEMPAS	40644		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

INITIAL CRITERIA:

The guideline named **PULMONARY ARTERIAL HTN - RIOCIQUAT (Adempas)** requires a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH) or pulmonary arterial hypertension (PAH). In addition, the following criteria must be met:

For chronic thromboembolic pulmonary hypertension (CTEPH), approval requires:

- The patient is 18 years of age or older
- Adempas is prescribed by or in consultation with a pulmonologist or cardiologist
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) for ALL of the following:
 - The patient has CTEPH as defined by WHO Group 4 pulmonary hypertension
 - The patient has ONE of the below:
 - Recurrent or persistent CTEPH after pulmonary endarterectomy (PEA) with a documented date of PEA **OR**
 - Inoperable CTEPH with the diagnosis confirmed by **BOTH** of the following:
 - Computed tomography (CT), magnetic resonance imaging (MRI), angiography or pulmonary angiography **AND**
 - Pretreatment right heart catheterization with all of the following results:
 - MPAP greater than or equal to 25 mmHg
 - PCWP less than or equal to 15 mmHg
 - PVR greater than 3 Wood Units

For pulmonary arterial hypertension (PAH), approval requires:

- The patient is 18 years of age or older
- Adempas is prescribed by or in consultation with a pulmonologist or cardiologist
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) for ALL of the following:
 - The patient has PAH as defined as WHO Group 1 pulmonary hypertension
 - The patient has PAH confirmed by right heart catheterization with the following pretreatment results:
 - MPAP greater than or equal to 25 mmHg
 - PCWP less than or equal to 15 mmHg
 - PVR greater than 3 Wood Units
 - The patient has NYHA functional Class II or III symptoms prior to initiation of Adempas therapy

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PULMONARY ARTERIAL HTN - RIOCIQUAT (MICHIGAN MEDICAID)

RENEWAL CRITERIA:

The guideline named **PULMONARY ARTERIAL HTN - RIOCIQUAT (Adempas)** requires a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH) or pulmonary arterial hypertension (PAH). In addition, the following must be met:

- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) that all of the initial authorization criteria has been met

RATIONALE

To ensure appropriate use of Adempas is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

ADEMPAS is indicated in adult patients with the following:

- Chronic Thromboembolic Pulmonary Hypertension (CTEPH) – that is persistent or recurrent, (WHO Group 4) after surgical treatment, or inoperable CTEPH, to improve exercise capacity and WHO functional class
- Pulmonary Arterial Hypertension (PAH) – to improve exercise capacity, WHO functional class and to delay clinical worsening

DOSAGE AND ADMINISTRATION

ADEMPAS starting dose recommendation is 1 mg taken orally 3 times a day. For patients who may not tolerate the hypotensive effect of Adempas, consider a starting dose of 0.5mg taken 3 times daily. Dose increases should be no sooner than 2 weeks apart.

For further dosage and administration, please refer to the Prescribing Information for Adempas.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- **Boxed Warning:** Embryo-fetal toxicity. **Category X.** All female patients obtain Riociguat through a restricted program called the Adempas risk evaluation and mitigation strategy (REMS) program. Obtain pregnancy tests in female patients prior to initiation and monthly during treatment.
- Co-administration with nitrates or nitric oxide donors (e.g., amyl nitrite) in any form
- Co-administration with phosphodiesterase (PDE) inhibitors, including specific PDE-5 inhibitors (e.g., sildenafil, tadalafil, vardenafil) or nonspecific PDE inhibitors (e.g., dipyridamole or theophylline)
- Concomitant therapy: Strong cytochrome P450 and P-glycoprotein/breast cancer resistance protein inhibitors (e.g. azole antifungals [such as ketoconazole, itraconazole], or protease inhibitors. [e.g. ritonavir])
- Renal function impairment: No dosage adjustment provided in manufacturer's labeling.
- Hepatic function impairment: (Child-Pugh A, B, and C) No dosage adjustment provided in the manufacturer's labeling

SPECIAL CONSIDERATIONS

- **Smokers:**
 - Consider titrating to greater than 2.5 mg three times daily, if tolerated. A decreased dose may be necessary in patients who stop smoking during therapy.
 - **REMS program:** Call 1-855-423-3672 or visit <http://www.AdempasREMS.com> for more information.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PULMONARY ARTERIAL HTN - RIOCIGUAT (MICHIGAN MEDICAID)

- **Hypotension:** Reduces blood pressure. Use with caution in patients at increased risk for symptomatic hypotension or ischemia (eg, patients with hypovolemia, severe left ventricular outflow obstruction, resting hypotension, autonomic dysfunction) or concurrent use of antihypertensives or strong CYP-450 and P-glycoprotein/breast cancer resistance protein inhibitors. Consider initiating at a lower dose for patients at risk of hypotension and/or dose reduction if hypotension develops.
- **Bleeding:** Serious bleeding has been observed.
- **Pulmonary veno-occlusive disease:** Use is not recommended in patients with pulmonary veno-occlusive disease. Discontinue in any patient with pulmonary edema suggestive of pulmonary veno-occlusive disease.
- **CNS effects:** Patients must be cautioned about performing tasks that require mental alertness (e.g., operating machinery or driving).
- **Hazardous agent:** Use appropriate precautions for handling and disposal (meets NIOSH 2014 criteria).

Appendix A: WHO Classification of Pulmonary Hypertension

The World Health Organization divides pulmonary hypertension (PH) into five groups. These groups are organized based on the cause of the condition. Note that group 1 is called pulmonary arterial hypertension (PAH) and groups 2 through 5 are called pulmonary hypertension. However, together all groups are called pulmonary hypertension.

Group 1 Pulmonary Arterial Hypertension (PAH) includes:

- Idiopathic - PAH that has no known cause.
- Heritable - PAH that is inherited (passed from parents to children through genes).
- Drug and Toxin induced -PAH that's caused by drugs or toxins, such as street drugs and certain diet medicines.
- PAH that is caused by conditions such as:
 - Connective tissue diseases
 - HIV infection
 - Liver disease
 - Congenital heart disease
 - Sickle cell disease
 - Schistosomiasis
- PAH that is caused by conditions that affect the veins and small blood vessels of the lungs.

Group 2 Pulmonary Hypertension with Left Heart Disease

- Conditions that affect the left side of the heart, such as:
 - Mitral valve disease
 - Long term high blood pressure

Group 3 Pulmonary Hypertension associated with Lung Diseases such as:

- Chronic obstructive pulmonary disease (COPD)
- Interstitial lung diseases
- Pulmonary Hypertension associated with sleep-related breathing disorders, such as obstructive sleep apnea, Cheyne-Stokes respiration (CSR) and central sleep apnea (CSA)

Group 4 Chronic Thromboembolic Pulmonary Hypertension (CTEPH) includes:

- PH caused by blood clots in the lungs
- PH caused by blood clotting disorders

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PULMONARY ARTERIAL HTN - RIOCIQUAT (MICHIGAN MEDICAID)

Group 5 Pulmonary Hypertension caused by various other diseases or conditions:

- Blood disorders, such as:
 - Polycythemia vera
 - Essential thrombocythemia
- Systemic disorders, such as:
 - Sarcoidosis
 - Vasculitis
- Metabolic disorders, such as:
 - Thyroid disease
 - Glycogen storage disease
- Other conditions, such as:
 - Tumors that press on the pulmonary arteries
 - Kidney disease

Appendix B: New York Heart Association Functional Classification

- **Class I:** Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.
- **Class II:** Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.
- **Class III:** Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.
- **Class IV:** Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

REFERENCES

- Adempas [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2018.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_5228_28_7.pdf [Accessed October 1, 2018].
- The Criteria Committee of the New York Heart Association. *Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels*. 9th ed. Boston, Mass: Little, Brown & Co; 1994:253-256.
- “Types of Pulmonary Hypertension” (2011, August 2). Retrieved from <http://www.nhlbi.nih.gov/health/health-topics/topics/pah/>

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PULMONARY ARTERIAL HTN – SILDENAFIL (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
SILDENAFIL	REVATIO		24758	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **PULMONARY ARTERIAL HTN – SILDENAFIL (Revatio)** requires a diagnosis of pulmonary arterial hypertension (PAH). In addition, the following criteria must be met:

For patients 18 years of age and older, approval requires:

- Revatio is prescribed by or in consultation with a pulmonologist or cardiologist
- The patient has PAH defined as WHO Group 1 pulmonary hypertension
- The patient has NYHA functional Class II or III symptoms
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of pre-treatment results from right heart catheterization, that includes the following:
 - MPAP greater than or equal to 25 mmHg
 - PCWP less than or equal to 15 mmHg
 - PVR greater than 3 Wood Units

For patients less than 18 years of age, approval requires:

- The patient is less than 18 years of age
- Revatio is prescribed by or in consultation with a pulmonologist or cardiologist
- The patient has PAH defined as WHO Group 1 pulmonary hypertension
- The patient has NYHA functional Class II or III symptoms
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of pre-treatment results from right heart catheterization, that includes the following (For infants less than one year of age with any of the following conditions, PAH was confirmed by Doppler echocardiogram if right heart catheterization cannot be performed.):
 - Post cardiac surgery
 - Chronic Heart Disease
 - Chronic lung disease associated with prematurity
 - Congenital diaphragmatic hernia

RENEWAL/DENIAL TEXT: The guideline named **PULMONARY ARTERIAL HTN – SILDENAFIL (Revatio)** requires a diagnosis of pulmonary arterial hypertension (PAH). In addition, the following criterion must be met:

- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) that all of the initial criteria has been met

RATIONALE

To ensure appropriate use of Revatio is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

REVATIO is indicated for the treatment of pulmonary arterial hypertension (WHO Group I) in adults to improve exercise ability and delay clinical worsening. The delay in clinical worsening was demonstrated when Revatio was added to background epoprostenol therapy.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PULMONARY ARTERIAL HTN – SILDENAFIL (MICHIGAN MEDICAID)

DOSAGE AND ADMINISTRATION

REVATIO dosing recommendation is 5 mg or 20 mg three times a day. Administer Revatio doses 4 to 6 hours apart. Treatment with doses higher than 20 mg three times a day is not recommended.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Use of organic nitrates medication (e.g. Nitroglycerin, isosorbide dinitrate) on a regular or intermittent basis is contra-indicated
- Concomitant treatment with guanylate cyclase stimulator (e.g. Adempas) is contraindicated.
- Hypersensitivity reaction to this product

SPECIAL CONSIDERATIONS

- **Renal function impairment:** No dosage adjustment required for any degree of impairment
- **Hepatic function impairment:** No need for dosage adjustment for mild to moderate impairment, has not been studied in patient with severe impairment
- **Cardiovascular disease:** Use cautiously in patient with hypotension; uncontrolled hypertension, life-threatening arrhythmias, stroke or MI within the last 6 months and other cardiac conditions
- Not recommended in patient with pulmonary veno-occlusive disease
- Risk of hearing loss, color discrimination, vision loss
- Safety in patients with sickle cell anemia, a bleeding disorder or peptic ulcer disease has not been established

Appendix A: WHO Classification of Pulmonary Hypertension

The World Health Organization divides pulmonary hypertension (PH) into five groups. These groups are organized based on the cause of the condition. Note that group 1 is called pulmonary arterial hypertension (PAH) and groups 2 through 5 are called pulmonary hypertension. However, together all groups are called pulmonary hypertension.

Group 1 Pulmonary Arterial Hypertension (PAH) includes:

- Idiopathic - PAH that has no known cause.
- Heritable - PAH that is inherited (passed from parents to children through genes).
- Drug and Toxin induced - PAH that is caused by drugs or toxins, such as street drugs and certain diet medicines.
- PAH that is caused by conditions such as:
 - Connective tissue diseases
 - HIV infection
 - Liver disease
 - Congenital heart disease
 - Sickle cell disease
 - Schistosomiasis
- PAH that is caused by conditions that affect the veins and small blood vessels of the lungs.

Group 2 Pulmonary Hypertension with Left Heart Disease

- Conditions that affect the left side of the heart, such as:
 - Mitral valve disease
 - Long term high blood pressure

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PULMONARY ARTERIAL HTN – SILDENAFIL (MICHIGAN MEDICAID)

Group 3 Pulmonary Hypertension associate with Lung Diseases such as:

- Chronic obstructive pulmonary disease (COPD)
- Interstitial lung diseases
- Pulmonary Hypertension associated with sleep-related breathing disorders, such as obstructive sleep apnea, Cheyne-Stokes respiration (CSR) and central sleep apnea (CSA)

Group 4 Chronic Thromboembolic Pulmonary Hypertension (CTEPH) includes:

- PH caused by blood clots in the lungs
- PH caused by blood clotting disorders

Group 5 Pulmonary Hypertension caused by various other diseases or conditions:

- Blood disorders, such as:
 - Polycythemia vera
 - Essential thrombocythemia
- Systemic disorders, such as:
 - Sarcoidosis
 - Vasculitis
- Metabolic disorders, such as:
 - Thyroid disease
 - Glycogen storage disease
- Other conditions, such as:
 - Tumors that press on the pulmonary arteries
 - Kidney disease

Appendix B: New York Heart Association Functional Classification

- **Class I:** Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.
- **Class II:** Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.
- **Class III:** Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.
- **Class IV:** Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PULMONARY ARTERIAL HTN – SILDENAFIL (MICHIGAN MEDICAID)

REFERENCES

- Revatio [Prescribing Information]. New York, NY: Pharmacia and Upjohn Co.; July 2018.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].
- The Criteria Committee of the New York Heart Association. *Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels*. 9th ed. Boston, Mass: Little, Brown & Co; 1994: 253-256.
- “Types of Pulmonary Hypertension” (2011, August 2). Retrieved from <http://www.nhlbi.nih.gov/health/health-topics/topics/pah/>

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PULMONARY ARTERIAL HTN - TADALAFIL (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
TADALAFIL	ADCIRCA		26587	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **TADALAFIL FOR PAH (Adcirca)** requires a diagnosis of Pulmonary Arterial Hypertension (PAH). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- Adcirca is prescribed by or in consultation with a pulmonologist or cardiologist
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of the following:
 - PAH is defined as WHO Group 1 pulmonary hypertension
 - Diagnosis is confirmed using a right heart catheterization test:
 - MPAP greater than or equal to 25mmHg
 - PCWP less than or equal to 15mmHg
 - PVR greater than 3 Wood units
 - The patient has NYHA functional Class II or III symptoms

RENEWAL CRITERIA:

The guideline named **PULMONARY ARTERIAL HTN - TADALAFIL (Adcirca)** requires a diagnosis of Pulmonary Arterial Hypertension (PAH). In addition, the following criterion must be met:

- The patient meets all the initial authorization criteria

RATIONALE

To ensure appropriate use of Adcirca is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

ADCIRCA is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability.

DOSAGE AND ADMINISTRATION

ADCIRCA dosage recommendation is 40mg (two 20mg tablets) taken once daily with or without food. Dividing the 40mg dose over the course of the day is not recommended.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Contraindicated in individuals with known hypersensitivity to tadalafil
- Concomitant use of organic nitrated or GC stimulators
- Use cautiously with mild to moderate renal insufficiency:
 - **Mild to moderate renal insufficiency** (Cr Clearance 31-80 mL/min): Initiate therapy with 20 mg daily; increase to 40 mg once daily based on individual tolerability
 - **Severe renal insufficiency** (Cr Clearance 30ml/min or less): Avoid use
 - End-stage renal disease requiring hemodialysis: Avoid use

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PULMONARY ARTERIAL HTN - TADALAFIL (MICHIGAN MEDICAID)

- Hepatic function Impairment:
 - **Mild or moderate hepatic impairment (Child-Pugh class A or B):** Use with caution. Consider a starting dosage of 20 mg per day
 - Severe hepatic cirrhosis (Child-Pugh class C): Avoid Use
- Use cautiously with ritonavir
 - **Initiation of tadalafil in patients currently receiving ritonavir for at least 1 week:** Initiate tadalafil at 20 mg once daily; increase to 40 mg once daily based on individual tolerability
 - **Initiation of ritonavir in patients currently receiving tadalafil:** Discontinue tadalafil at least 24 hours prior to the initiation of ritonavir. After at least 1 week of ritonavir, resume tadalafil at 20 mg once daily; increase to 40 mg once daily based on individual tolerability

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION (CONTINUED)

- Do not use if taking rifampin or ketoconazole
- If sudden loss of vision in one or both eyes or sudden decrease of hearing and or dizziness, patient must seek immediate medical attention
- Prolonged erectile dysfunction, seek medical attention.

SPECIAL CONSIDERATIONS

- Tadalafil has been used off label to treat Raynaud's phenomenon. It may be used as monotherapy or as adjunctive therapy to vasodilator therapy (e.g., calcium channel blockers, angiotensin receptor blockade).

Appendix A: WHO Classification of Pulmonary Hypertension

The World Health Organization divides pulmonary hypertension (PH) into five groups. These groups are organized based on the cause of the condition. Note that group 1 is called pulmonary arterial hypertension (PAH) and groups 2 through 5 are called pulmonary hypertension. However, together all groups are called pulmonary hypertension.

Group 1 Pulmonary Arterial Hypertension (PAH) includes:

- Idiopathic - PAH that has no known cause.
- Heritable - PAH that is inherited (passed from parents to children through genes).
- Drug and Toxin induced - PAH that is caused by drugs or toxins, such as street drugs and certain diet medicines.
- PAH that's caused by conditions such as:
 - Connective tissue diseases
 - HIV infection
 - Liver disease
 - Congenital heart disease
 - Sickle cell disease
 - Schistosomiasis
- PAH that is caused by conditions that affect the veins and small blood vessels of the lungs.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PULMONARY ARTERIAL HTN - TADALAFIL (MICHIGAN MEDICAID)

Group 2 Pulmonary Hypertension with Left Heart Disease

- Conditions that affect the left side of the heart, such as:
 - Mitral valve disease
 - Long term high blood pressure

Group 3 Pulmonary Hypertension associate with Lung Diseases such as:

- Chronic obstructive pulmonary disease (COPD)
- Interstitial lung diseases
- Pulmonary Hypertension associated with sleep-related breathing disorders, such as obstructive sleep apnea, Cheyne-Stokes respiration (CSR) and central sleep apnea (CSA)

Group 4 Chronic Thromboembolic Pulmonary Hypertension (CTEPH) includes:

- PH caused by blood clots in the lungs
- PH caused by blood clotting disorders

Appendix A (continued)

Group 5 Pulmonary Hypertension caused by various other diseases or conditions:

- Blood disorders, such as:
 - Polycythemia vera
 - Essential thrombocythemia
- Systemic disorders, such as:
 - Sarcoidosis
 - Vasculitis
- Metabolic disorders, such as:
 - Thyroid disease
 - Glycogen storage disease
- Other conditions, such as:
 - Tumors that press on the pulmonary arteries
 - Kidney disease

Appendix B: New York Heart Association Functional Classification

- **Class I:** Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.
- **Class II:** Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.
- **Class III:** Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.
- **Class IV:** Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PULMONARY ARTERIAL HTN - TADALAFIL (MICHIGAN MEDICAID)

REFERENCES

- Adcirca [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; August 2017.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].
- The Criteria Committee of the New York Heart Association. *Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels*. 9th ed. Boston, Mass: Little, Brown & Co; 1994: 253-256.
- “Types of Pulmonary Hypertension” (2011, August 2). Retrieved from <http://www.nhlbi.nih.gov/health/health-topics/topics/pah/>

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P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PALIVIZUMAB (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
PALIVIZUMAB	SYNAGIS	18564		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL APPROVAL:

The guideline named **PALIVIZUMAB (Synagis)** is being requested for use in the prevention of respiratory syncytial virus (RSV) in children 24 months and younger at high risk of RSV disease. Coverage of Synagis under the pharmacy benefit requires that the patient lives in a rural county within Michigan. In addition, the following criteria must be met as documented by labs, medical record, special studies and/or physician attestation:

For Prematurity, approval requires:

- Infants who are younger than 12 months of age at the start of the Synagis season and who are born before 29 weeks, 0 days' gestation

For Chronic Lung Disease (CLD), approval requires **ONE** of the following:

- Infants in the first 12 months of life, who are diagnosed with Chronic Lung Disease (CLD) of prematurity defined as birth at < 32 weeks, 0 days' gestation and a requirement for >21% oxygen for at least 28 days after birth **OR**
- Infants in the second year of life who are diagnosed with CLD (as per above criteria) **AND** who continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy) within the 6-month period before the start of the second RSV season

For Heart Disease, approval requires:

- Children who are 12 months or younger with hemodynamically significant CHD as evidenced by:
 - Acyanotic heart disease and are receiving medication to control congestive heart failure, and will require cardiac surgical procedures

For Pulmonary Hypertension, approval requires:

- Infants with moderate to severe pulmonary hypertension. Children with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretion from the upper airways may be considered for prophylaxis in the first year of life.

For the immunocompromised, approval requires:

- Child younger than 24 months who will be profoundly immunocompromised during the RSV season

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MCLAREN HEALTH PLAN MEDICAID PRIOR AUTHORIZATION GUIDELINES

PALIVIZUMAB (MICHIGAN MEDICAID)

RATIONALE

To ensure appropriate use of Synagis is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

SYNAGIS is indicated for the prevention of serious lower respiratory tract disease caused by Respiratory Syncytial Virus (RSV) in pediatric patients with:

- A history of premature birth (\leq 35 weeks gestational age) and who are 6 months of age or younger at the beginning of RSV season
- Bronchopulmonary dysplasia (BPD) that require medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of RSV season
- Hemodynamically significant Congenital Heart Disease (CHD) and who are 24 months of age or younger at the beginning of RSV season

Limitation of Use:

The safety and efficacy of Synagis have not been established for treatment of RSV disease.

DOSAGE AND ADMINISTRATION

The recommended dose of Synagis is 15mg/kg of body weight given monthly by intramuscular injection. The first dose of Synagis should be administered prior to commencement of the RSV season and the remaining doses should be administered monthly throughout the RSV season. Children who develop an RSV infection should continue to receive monthly doses throughout the RSV season. In the northern hemisphere, the RSV season typically commences in November and lasts through April, but it may begin earlier or persist later in certain communities.

For further details about the dosage and administration, please refer to the Prescribing Information for Synagis.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- History of severe prior reaction to palivizumab or any component of the formulation
- In addition, drug therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

SPECIAL CONSIDERATIONS

- Synagis is only covered under the pharmacy benefit for members residing in rural Michigan counties.
- Routine use in cystic fibrosis and Down Syndrome is not recommended.
- The clinical reviewer, in his or her professional judgment, will override criteria when the requested item is medically necessary. In addition, because there is no definite evidence for the treatment of patients undergoing stem cell transplant or infants and children with Cystic Fibrosis, the approval of Synagis for these patients will be done on a case-by-case basis by the clinical reviewer.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PALIVIZUMAB (MICHIGAN MEDICAID)

REFERENCES

- Synagis [Prescribing Information]. Gaithersburg, MD: MedImmune, LLC; May 2017.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].
- American Academy of Pediatrics, Committee on Infectious Diseases and Bronchiolitis Guideline Committee. Policy Statement: updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. *Pediatrics*.2014;134(2): 415-420.
- Palivizumab. In: G.K. McEvoy et al. (Eds.), American Hospital Formulary Service Drug Information. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.
- Subcommittee on Diagnosis and Management of Bronchiolitis. Diagnosis and management of bronchiolitis clinical practice guideline. *Pediatrics*. 2006;118(4): 1174-1793, Available from <http://aappolicy.aappublications.org/cgi/reprint/pediatrics;118/4/1774.pdf>.
- Synagis. In: DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.

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Client Approval: 12/11/18

P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PENTOSAN POLYSULFATE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
PENTOSAN POLYSULFATE	ELMIRON		41229	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **PENTOSAN POLYSULFATE SODIUM (Elmiron)** requires a diagnosis of interstitial cystitis and documentation (e.g. labs, medical record, special studies, and/or physician attestation) confirming the diagnosis of interstitial cystitis.

RENEWAL CRITERIA:

The guideline named **PENTOSAN POLYSULFATE (Elmiron)** requires the diagnosis of interstitial cystitis for renewal. In addition, the following criteria must be met as documented by e.g. labs, medical record, special studies, and/or physician attestation:

1. The patient has experienced improvement in pain after 3 months of therapy
2. The patient does not have adverse events

RATIONALE

To ensure appropriate use of pentosan (Elmiron) consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

Elmiron is indicated for the relief of bladder pain or discomfort associated with interstitial cystitis.

DOSAGE AND ADMINISTRATION

The recommended dose of Elmiron is 300mg per day taken as one 100mg capsule orally three times daily. The capsules should be taken with water at least one hour before meals or 2 hours after meals.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REFERENCES

- Elmiron [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; May 2018.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PIMECROLIMUS (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
PIMECROLIMUS	ELIDEL	23167		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **PIMECROLIMUS (Elidel)** requires a diagnosis of mild to moderate atopic dermatitis. In addition, the following criteria must be met.

- The patient is 2 years of age or older
- The requested medication will be used for short-term treatment
- The patient is NOT immunocompromised
- There is documentation of ALL of the following:
 - The patient has tried and failed topical moisturizers or emollients
 - The patient has tried and failed oral / systemic medications such as antihistamines (first or second generation) and antipruritics (e.g., hydroxyzine)
 - The patient has avoided triggers due to diet, irritants (soaps, detergents, etc.), fabrics
 - The patient has tried and failed at least two topical steroids, to include up to a medium strength product, **OR** there is a clinical reason why treatment with a moderate to high potency topical steroid is not appropriate (e.g. inadequate response, skin atrophy, or use on an area of the body at high risk for skin atrophy, such as the face or skin folds)
 - Areas of involvement (face, trunk, back, etc.) and percentage of body involved

RENEWAL CRITERIA:

The guideline named **PIMECROLIMUS (Elidel)** requires a diagnosis of mild to moderate atopic dermatitis. In addition, there must be documentation of **ALL** of the following:

- Therapy is prescribed by or in consultation with a specialist
- The patient has been reexamined to confirm the diagnosis of atopic dermatitis if signs and symptoms persist longer than 6 weeks
- The patient has NOT received a total of 3 months treatment

RATIONALE

To ensure appropriate use of Elidel is consistent with FDA approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATION

Elidel Cream, 1% is indicated as second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PIMECROLIMUS (MICHIGAN MEDICAID)

DOSAGE AND ADMINISTRATION

Apply a thin layer of Elidel Cream, 1% to the affected skin twice daily. The patient should stop using Elidel Cream when signs and symptoms (e.g., itch, rash and redness) resolve and should be instructed on what actions to take if symptoms recur. If signs and symptoms persist beyond 6 weeks, patients should be re-examined by their healthcare provider to confirm the diagnosis of atopic dermatitis. Continuous long-term use of Elidel Cream, 1% should be avoided, and application should be limited to areas of involvement with atopic dermatitis. The safety of Elidel Cream, 1% under occlusion, which may promote systemic exposure, has not been evaluated. Avoid use of ELIDEL Cream, 1% with occlusive dressings.

CONTRAINDICATION/EXCLUSION/DISCONTINUATION

- Not for chronic use
- Elidel® is not recommended for use on patients with Netherton's syndrome due to the potential for systemic absorption.
- Not recommended (especially Elidel®) for use in immunocompromised patients
- Should not be applied to infected skin whether bacterial, viral, or fungal
- Although a causal relationship has not been established, rare cases of malignancy (e.g., skin malignancy, lymphoma) have been reported in patients treated with topical calcineurin inhibitors, including pimecrolimus. Therefore, avoid continuous, long-term use of topical calcineurin inhibitors, including pimecrolimus, in any age group, and limit application to areas of involvement with atopic dermatitis.
- Pimecrolimus is not indicated for use in children younger than 2 years
- In addition, therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

OTHER SPECIAL CONSIDERATIONS

Off-label use for the following have been reported:

- Lichen planus (oral)
- Psoriasis
- Rosacea
- Vitiligo

REFERENCES

- Elidel [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; December 2017.
- McLaren Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PYRIMETHAMINE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
PYRIMETHAMINE	DARAPRIM	04150		ROUTE ≠ MISCELL.

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **PYRIMETHAMINE (Daraprim)** requires that the request is for the treatment of toxoplasmosis or secondary prevention of toxoplasmosis in a patient with HIV, or prevention/prophylaxis of pneumocystis pneumonia in a patient with HIV. In addition, the following criteria must be met.

For treatment of toxoplasmosis or secondary prevention of toxoplasmosis in a patient with HIV, approval requires:

- Therapy is prescribed by or in consultation with an infectious disease specialist

For prevention/prophylaxis of pneumocystis pneumonia in a patient with HIV, approval requires:

- Therapy is prescribed by or in consultation with an infectious disease specialist
- There is documentation of previous trial of TMP/SMX, atovaquone, and dapsone
- There is documentation of ONE of the following:
 - The patient has CD4 count <200 cells/microL
 - The patient has oropharyngeal candidiasis
 - The patient's CD4 count percentage is <14 percent
 - The patient's CD4 cell count is between 200 and 250 cells/microL IF frequent monitoring (e.g., every three months) of CD4 cell counts is not possible

RENEWAL CRITERIA:

The guideline named **PYRIMETHAMINE (Daraprim)** requires that the request is for the prophylaxis of toxoplasmosis in a patient with HIV, or prophylaxis of pneumocystis pneumonia in a patient with HIV. In addition, the following criteria must be met.

For prophylaxis of toxoplasmosis in a patient with HIV, approval requires **ONE** of the following:

- The patient remains symptomatic
- The patient is NOT receiving antiretroviral therapy (ART)
- The patient has a detectable HIV viral load
- The patient has maintained a CD4 count >200 cells/microL for less than six months

For prophylaxis of pneumocystis pneumonia in a patient with HIV, approval requires **ONE** of the following:

- The patient has CD4 count <200 cells/microL
- The patient has oropharyngeal candidiasis
- The patient's CD4 count percentage is <14 percent
- The patient's CD4 cell count is between 200 and 250 cells/microL IF frequent monitoring (e.g., every three months) of CD4 cell counts is not possible

RATIONALE

To ensure appropriate use of Daraprim consistent with FDA approved indications and Michigan Medicaid requirements.

CONTINUE ON NEXT PAGE

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

PYRIMETHAMINE (MICHIGAN MEDICAID)

FDA APPROVED INDICATION

Daraprim is indicated for the treatment of toxoplasmosis when used conjointly with a sulfonamide, since synergism exists with this combination.

DOSAGE AND ADMINISTRATION

The dosage of Daraprim for the treatment of toxoplasmosis must be carefully adjusted so as to provide maximum therapeutic effect and a minimum of side effects. At the dosage required, there is a marked variation in the tolerance to the drug. Young patients may tolerate higher doses than older individuals. Concurrent administration of folic acid is strongly recommended in all patients.

The adult starting dose is 50 to 75 mg of the drug daily, together with 1 to 4 g daily of a sulfonamide of the sulfapyrimidine type, e.g. sulfadoxine. This dosage is ordinarily continued for 1 to 3 weeks, depending on the response of the patient and tolerance to therapy. The dosage may then be reduced to about one half that previously given for each drug and continued for an additional 4 to 5 weeks. The pediatric dosage of DARAPRIM is 1 mg/kg/day divided into 2 equal daily doses; after 2 to 4 days this dose may be reduced to one half and continued for approximately 1 month. The usual pediatric sulfonamide dosage is used in conjunction with Daraprim.

CONTRAINDICATION/EXCLUSION/DISCONTINUATION

- Megaloblastic anemia due to folate deficiency
- Secondary prophylaxis of Toxoplasmosis in patients with a CD4 count >200 cells/microL for longer than 6 months and a sustained HIV viral load
- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy

OTHER SPECIAL CONSIDERATIONS

- Daraprim is no longer recommended for malaria treatment or prophylaxis and treatment of malaria is very individualized.
- Refer to the CDC website for recommendations for treatment and prevention of malaria.

REFERENCES

- Daraprim [Prescribing Information]. New York, NY: Viera Pharmaceuticals LLC; August 2017.
- McLaren Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

RANOLAZINE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
RANOLAZINE	RANEXA	33446		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **RANOLAZINE (Ranexa)** requires a diagnosis of chronic stable angina. In addition, the following criteria must be met:

- The patient is 18 years of age or older
- Ranexa is prescribed by or in consultation with a cardiologist
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of ALL of the following:
 - Diagnosis of chronic angina
 - The patient has had a trial of at least **ONE** formulary anti-anginal agent from **ALL 3** different drug classes:
 - **Beta-blocker:** acebutolol, atenolol, carvedilol, metoprolol, nadolol, propranolol
 - **Caclium channel blocker:** amlodipine, diltiazem, felodipine, isradipine, nifedipine, nicardipine, verapamil
 - **Long acting nitrate:** isosorbide dinitrate, isosorbide mononitrate, nitroglycerin patch
 - Ranexa will be used in addition (add-on) to another anti-anginal medication (i.e., beta-blocker, calcium channel blockers and long-acting nitrates)

RENEWAL CRITERIA:

The guideline named **RANOLAZINE (Ranexa)** requires a diagnosis of chronic stable angina. In addition, the following criterion must be met as documented by e.g. labs, medical record, special studies and/or physician attestation:

- Demonstrated efficacy and safety while on Ranexa therapy

RATIONALE

To ensure appropriate use of Ranexa is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

RANEXA is indicated for the treatment of chronic angina.

RANEXA may be used with beta-blockers, nitrates, calcium channel blockers, anti-platelet therapy, lipid-lowering therapy, ACE inhibitors, and angiotensin receptor blockers.

DOSAGE AND ADMINISTRATION

RANEXA initial dosing recommendation is 500 mg twice daily and increase to 1000 mg twice daily, as needed, based on clinical symptoms. Take Ranexa with or without meals. Swallow Ranexa tablets whole; do not crush, break, or chew. The maximum recommended daily dose of Ranexa is 1000 mg twice daily.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

RANOLAZINE (MICHIGAN MEDICAID)

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Hepatic impairment (Child-Pugh Classes A and B)
- Combined administration with other drugs that are strong inhibitors of CYP3A including ketoconazole, itraconazole, clarithromycin, nefazodone, nelfinavir, ritonavir, indinavir, and saquinavir
- Combined administration with other drugs that are inducers of CYP3A including rifampin, rifabutin, phenobarbital, phenytoin, carbamazepine, and St. John's wort
- Moderate to severe renal impairment CrCl < 60mL/min

SPECIAL CONSIDERATIONS

- Not for initial therapy because it can increase QT interval

REFERENCES

- Ranexa [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; January 2016.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

RIVAROXABAN (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
RIVAROXABAN	XARELTO	35915		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **RIVAROXABAN (Xarelto)** requires patients to be 18 years of age or older and that the requested medication is being used for the reduction in the risk of stroke and systemic embolism in patients with non-valvular Atrial Fibrillation (A-fib), treatment of Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE), for DVT prophylaxis in patients undergoing knee or hip replacement surgery, or for reducing the risk of DVT/PE recurrence in patients at continued risk. In addition, the following criteria must be met (as documented by labs, medical record, special studies and/or physician attestation):

For reduction in the risk of stroke and systemic embolism in patients with non-valvular Atrial Fibrillation (A-fib), approval requires:

- The patient was started on Xarelto therapy in the hospital and was discharged while on therapy
- The patient has a diagnosis of non-valvular atrial fibrillation
- The patient has tried and failed or has an intolerance to warfarin therapy
- The patient has moderate to high risk for stroke as determined by **ONE** the following:
 - The patient has a history of stroke, Transient Ischemic Attack (TIA), or systemic embolism
 - OR**
 - The patient has **TWO** of the following:
 - Heart failure or Left Ventricular Ejection Fraction (LVEF) equal to or less than 35%
 - Hypertension (HTN)
 - 75 years of age or older
 - Diabetes Mellitus (DM)

For the treatment of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), approval requires:

- The patient was started on Xarelto therapy in the hospital and was discharged while on therapy
- The patient has a DVT or PE
- The patient has tried and failed or has an intolerance to warfarin therapy

For DVT prophylaxis in patients undergoing knee or hip replacement surgery, approval requires:

- The patient was started on Xarelto therapy in the hospital and was discharged while on therapy
- The patient has undergone elective total hip arthroplasty or total knee arthroplasty

For reducing the risk of DVT and/or PE recurrence in patients at continued risk for recurrence of DVT and/or PE, no additional criteria is required for initial approval.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

RIVAROXABAN (MICHIGAN MEDICAID)

RENEWAL CRITERIA:

The guideline named **RIVAROXABAN (Xarelto)** requires the requested medication to be used for reduction in risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation (A-fib), for DVT prophylaxis following knee or hip replacement surgery, or for reducing the risk of DVT/PE recurrence in patients at continued risk.

In addition, the following criteria must be met as documented by labs, medical record, special studies and/or physician attestation:

For reduction in the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation (A-fib) or for DVT prophylaxis following knee or hip replacement surgery, approval requires:

- The patient is tolerating and responding to medication
- There continues to be a medical need for the medication
- The patient's creatinine clearance (CrCL) is being monitored

For reducing the risk of DVT and/or PE recurrence in patients at continued risk for recurrence of DVT and/or PE, approval requires:

- The patient is tolerating and responding to treatment

RATIONALE

To ensure appropriate use of rivaroxaban (Xarelto) is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

XARELTO is indicated for the following:

- To reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation
- For the treatment of deep vein thrombosis (DVT)
- For the treatment of pulmonary embolism (PE)
- For the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery
- For the reduction in the risk of recurrence of DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months

DOSAGE AND ADMINISTRATION

XARELTO dosing recommendations are as follows:

Indication	Dosage (and duration where applicable)
Reduction in risk of stroke in non-valvular Atrial Fibrillation	CrCl > 50mL/min: 20mg once dail with evening meal CrCl 15-50mL/min: 15mg once daily with evening meal
Treatment of DVT/PE	15mg twice daily with food, for first 21 days then transition to 20mg once daily with food, for the remainder of treatment
Reduction in Risk of Recurrence of DVT and/or PE in patients at continued risk for DVT and/or PE	10mg once daily with or without food, after at least 6 months of standart anticoagulant treatment
Prophylaxis of DVT following hip or knee replacement surgery	Hip replacement: 10mg once dailt with or without food, for 35 days Kee replacement: 10mg once dailt with or without food, for 12 days

The 15mg and 20mg strengths of Xarelto tablets should be taken with food, while the 10mg table can be taken without regard to food intake. For further details, please refer to the prescribing information for Xarelto.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

RIVAROXABAN (MICHIGAN MEDICAID)

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- **BOX Warning:**
 - Discontinuing Xarelto can lead to higher risk of stroke (if discontinuation is warranted for reasons other than pathological bleeding, consider the use of another anticoagulation agent).
 - Administration of Xarelto while also receiving neuraxial anesthesia or undergoing spinal puncture can lead to epidural or spinal hematomas, which can result in long term or permanent paralysis.
 - If discontinuation is warranted due to risk of bleeding with surgery or other procedures, temporarily stop Xarelto at least 24 hours before procedure. Restart after the procedure once adequate hemostasis has been established.
 - Avoid in CrCl < 15 ml/min.
 - Per the Beers Criteria, for patients older than 65, avoid Xarelto if CrCl < 30 ml/min
 - Avoid use with P-gp and strong CYP3A4 inhibitors/inducers.
- Active pathological bleeding
- Hypersensitivity reaction to Xarelto
- The patient is noncompliant with medical or pharmacologic therapy
- The patient has no demonstrable clinically significant improvement in condition that has occurred after the initiation of drug therapy

SPECIAL CONSIDERATIONS

- There is no specific antidote available for Xarelto.

REFERENCES

- Xarelto [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; August 2018.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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P&T Approval: N/A

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

SACUBITRIL-VALSARTAN (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
SACUBITRIL-VALSARTAN	ENTRESTO	42256		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **SACUBITRIL-VALSARTAN (Entresto)** requires a diagnosis of heart failure. In addition, the following criteria must be met:

- Therapy is prescribed by or in consultation with a board-certified cardiologist
- The patient is 18 years of age or older
- There is documentation (e.g., labs, medical record [including hospitalizations], special studies and/or physician attestation) of ALL the following criteria:
 - No evidence of severe hepatic impairment (Child Pugh Class C)
 - Heart failure NYHA Class II-IV
 - Reduced ejection fraction (HFrEF) of 35% or less
 - Systolic BP is 100mmHg or higher
 - eGFR is 30mL/min/1.73m² or higher
 - The patient is tolerating an ACEI or ARB at HIGH doses (equivalent to at least enalapril 10mg BID) for at least 4 weeks (Entresto will replace the ACEI and/or ARB, after 36 hour washout)
 - The patient is currently on spironolactone or other diuretic for at least 4 weeks **AND** a beta-blocker at a MAXIMAL tolerated dose for at least 4 weeks (or provide clinical reasoning; adverse reaction, intolerance to higher doses to why a maximal dosed beta-blocker is inappropriate) and has not achieved improvement functional class or has worsening symptoms.

RENEWAL CRITERIA:

The guideline named **SACUBITRIL-VALSARTAN (Entresto)** requires a diagnosis of heart failure for renewal. In addition, the following criteria must be met:

- There is documentation (e.g., labs, medical record, special studies and/or physician attestation) of BOTH of the following:
 - The patient has had a positive response to therapy
 - The patient is adherent to all medications for heart failure

RATIONALE

To ensure appropriate use of Entresto consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

- Entresto is a combination of sacubitril, a neprilysin inhibitor, and valsartan, an angiotensin II receptor blocker, indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction.
- Entresto is usually administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other ARB.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

SACUBITRIL-VALSARTAN (MICHIGAN MEDICAID)

DOSAGE AND ADMINISTRATION

- The recommended starting dose of Entresto is 49/51mg (sacubitril/valsartan) twice daily.
- Reduce the starting dose to 24/26mg (sacubitril/valsartan) twice daily for:
 - Patients not currently taking an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin II receptor blocker (ARB) or previously taking a low dose of these agents
 - Patients with severe renal impairment
 - Patients with moderate hepatic impairment
- Double the dose of Entresto after two to four weeks to the target maintenance dose 97/103mg (sacubitril/valsartan) twice daily, as tolerated by the patient.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Pregnancy
- Severe hepatic impairment (Child Pugh Class C)
- Non - adherence to therapy
- History of angioedema

REFERENCES

- Entresto [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation.; November 2017.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

SEVELAMER (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
SEVELAMER	REVELA, RENAGEL		16853 99200	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **SEVELAMER (Renvela)** requires a diagnosis of chronic kidney disease (CKD) requiring dialysis. In addition, the following criteria must be met:

- The patient is 6 years of age or older
- The requested medication is being prescribed by or in consultation with a nephrologist
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) for **BOTH** of the following:
 - The patient has hyperphosphatemia
 - The patient has had a trial and failure of calcium acetate (elevated phosphorous or calcium levels for consecutive measurements)

INITIAL CRITERIA:

The guideline named **SEVELAMER (Renagel)** requires a diagnosis of chronic kidney disease (CKD) requiring dialysis. In addition, the following criteria must be met:

- The patient is 18 years of age or older
- The requested medication is being prescribed by or in consultation with a nephrologist
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) for **BOTH** of the following:
 - The patient has hyperphosphatemia
 - The patient has had a trial and failure of calcium acetate (elevated phosphorous or calcium levels for consecutive measurements)

RENEWAL CRITERIA:

The guideline named **SEVELAMER (Renvela & Renagel)** requires a diagnosis of hyperphosphatemia with chronic kidney disease (CKD) requiring dialysis. In addition, the following criteria must be met:

- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of serum phosphorus

SEVELAMER (MICHIGAN MEDICAID)

RATIONALE

To ensure appropriate use of Renvela and Renagel is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

REVELA (sevelamer carbonate) is indicated for the control of serum phosphorus in adults and children 6 years of age and older with chronic kidney disease (CKD) on dialysis.

RENAGEL (sevelamer hydrochloride) is indicated for the control of serum phosphorus in patients with chronic kidney disease (CKD) on dialysis.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

SEVELAMER (MICHIGAN MEDICAID)

Limitation of Use:

- The safety and efficacy of RENAGEL in CKD patients who are not on dialysis have not been studied.

DOSAGE AND ADMINISTRATION

REVELA starting dose recommendation for patients on dialysis switching from calcium acetate to renvela is as follows:

Calcium Acetate 667 mg (tablets per meal)	Renvela Dose
1 tablet	1 tablet (0.8 grams)
2 tablets	2 tablets (1.6 grams)
3 tablets	3 tablets (2.4 grams)

For further information about dosage and administration, please refer to the Prescribing Information for Renvela.

RENAGEL starting dose recommendation for patients on dialysis switching from calcium acetate to Renagel is as follows:

Calcium Acetate 667 mg (tablets per meal)	Renagel 800 mg (tablets per meal)	Renagel 400 mg (tablets per meal)
1 tablet	1 tablet	2 tablets
2 tablets	2 tablets	3 tablets
3 tablets	3 tablets	5 tablets

For further information about dosage and administration, please refer to the Prescribing Information for Renagel.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Bowel obstruction
- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy
- No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy

REFERENCES

- Renvela [Prescribing Information]. Cambridge, MA: Genzyme Corporation; July 2018.
- Renagel [Prescribing Information]. Cambridge, MA: Genzyme Corporation; April 2017.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

SGLT-2 INHIBITOR (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
CANAGLIFLOZIN	INVOKANA	40171		
EMPAGLIFLOZIN	JARDIANCE	41217		
ERTUGLIFLOZIN	STEGLATRO	44709		

This drug requires a written request for prior authorization.

INITIAL CRITERIA:

The guideline named **SGLT-2 INHIBITOR (Invokana, Jardiance and Steglatro)** requires a diagnosis of type 2 diabetes mellitus (DM). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) for **BOTH** of the following:
 - The patient has had a trial, failure or intolerance to metformin **AND** a formulary sulfonylurea, thiazolidinedione (TZD) or dipeptidyl peptidase-4 inhibitor (DPP-4 inhibitor) drug in the past 120 days
 - The patient has a hemoglobin A1c equal to or less than 9%

RENEWAL CRITERIA:

The guideline named **SGLT-2 INHIBITOR (Invokana, Jardiance and Steglatro)** requires a diagnosis of type 2 diabetes mellitus (DM). In addition, the following criteria must be met as documented by labs, medical record, special studies and/or physician attestation:

- The patient is responding therapy
- The patient is tolerating treatment
- The patient has an eGFR greater than 45ml/min/1.73m²

RATIONALE

To ensure appropriate use of Invokana, Jardiance and Steglatro is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

INVOKANA and STEGLATRO are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (DM).

JARDIANCE is indicated for the following:

- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (DM)
- To reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus (DM) and established cardiovascular disease

Limitation of Use:

JARDIANCE is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

SGLT-2 INHIBITOR (MICHIGAN MEDICAID)

DOSAGE AND ADMINISTRATION

The recommended dosage of INVOKANA is as follows:

- The recommended starting dose is 100mg orally once daily, taken before the first meal of the day.
- For patients tolerating Invokana 100mg once daily, who have an eGFR $\geq 60\text{ml/min}/1.73\text{m}^2$ and who require additional glycemic control, the dose can be increased to 300mg once daily.
- In patients with volume depletion, correcting this condition prior to initiation of Invokana is recommended.

For further dosage and administration details, please refer to the Prescribing Information for Invokana.

The recommended dosage of JARDIANCE is as follows:

- The recommended dose of Jardiance is 10mg orally once daily in the morning, taken with or without food.
- In patients with volume depletion, correcting this condition prior to initiation of Jardiance is recommended.

For further dosage and administration details, please refer to the Prescribing Information for Jardiance.

The recommended dosage of STEGLATRO is as follows:

- The recommended dose of Steglatro is 5mg orally once daily in the morning, taken with or without food.
- In patients with volume depletion, correcting this condition prior to initiation of Steglatro is recommended.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Hypersensitivity to canagliflozin or any component of the formulation
- Severe renal impairment (eGFR $< 30\text{ml/minute}/1.73\text{m}^2$)
- End-stage renal disease
- The patient is on dialysis
- In addition, therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy
- The patient demonstrates no clinically significant improvement in condition after initiation of drug therapy

REFERENCES

- Invokana [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; September 2018.
- Jardiance [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; December 2017.
- Steglatro [Prescribing Information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; December 2017.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

SGLT-2 INHIBITOR COMBINATION (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
CANAGLIFLOZIN/METFORMIN HCL	INVOKAMET XR INVOKAMET	41287		
EMPAGLIFLOZIN/METFORMIN HCL	SYNJARDY XR SYNJARDY	42183		
ERTUGLIFLOZIN/METFORMIN HCL	SEGLUROMET	44716		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **SGLT-2 INHIBITOR COMBINATION (Invokamet, Invokamet XR, Synjardy, Synjardy XR, and Segluromet)** requires a diagnosis of Type 2 Diabetes Mellitus (DM). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) for **BOTH** of the following:
 - The patient has had a clinically successful treatment with individual components of the requested medication for at least 60 days of the most recent 120 days
 - The patient has a hemoglobin A1c equal to or less than 9%

RENEWAL CRITERIA:

The guideline named **SGLT-2 INHIBITOR COMBINATION (Invokamet, Invokamet XR, Synjardy, Synjardy XR, and Segluromet)** requires a diagnosis of type 2 diabetes mellitus (DM). In addition, the following must criteria must be met as documented by labs, medical record, special studies and/or physician attestation:

- The patient is responding to treatment
- The patient is tolerating treatment

RATIONALE

To ensure appropriate use of Invokamet, Invokamet XR, Synjardy, Synjardy XR and Segluromet are consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

INVOKAMET (canagliflozin and metformin hydrochloride) and INVOKAMET XR (canagliflozin and metformin hydrochloride extended release) are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (DM) when both canagliflozin and metformin is appropriate.

SYNJARDY (empagliflozin and metformin hydrochloride) and SYNJARDY XR (empagliflozin and metformin hydrochloride extended release) are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (DM) when treatment with both empagliflozin and metformin hydrochloride is appropriate.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

SGLT-2 INHIBITOR COMBINATION (MICHIGAN MEDICAID)

Empagliflozin is indicated to reduce the risk of cardiovascular death in adult patients with Type 2 Diabetes Mellitus (DM) and established cardiovascular disease. However, the effectiveness of Synjardy and Synjardy XR on reducing the risk of cardiovascular death in adults with Type 2 Diabetes Mellitus (DM) and cardiovascular disease has not been established.

SEGLUROMET (ertugliflozin and metformin hydrochloride) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (DM) when both ertugliflozin and metformin hydrochloride is appropriate.

FDA APPROVED INDICATIONS (CONTINUED)

Limitation of Use:

Invokana, Invokana XR, Synjardy, Synjardy XR and Segluromet are not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

DOSAGE AND ADMINISTRATION

INVOKAMET dosing is based on the effectiveness and tolerability of the patient's current regimen and one dosage recommendation is as follows:

- INVOKAMET tablet twice daily with meals; in patients tolerating canagliflozin 50 mg twice daily who have an eGFR of 60 mL/min/1.73m² or greater and require additional glycemic control, INVOKAMET dose can be increased for the canagliflozin component to 150 mg twice daily, with gradual metformin dose escalation to reduce the gastrointestinal side effects due to metformin.

For further dosage and administration details, please refer to the Prescribing Information for Invokamet.

The recommended dosage of INVOKAMET XR is as follows:

- Individualize the starting dose of INVOKAMET XR (canagliflozin and metformin hydrochloride extended-release), taken once daily with the morning meal, based on the effectiveness and tolerability of the patient's current regimen.

For further dosage and administration details, please refer to the Prescribing Information for Invokamet XR.

SYNJARDY dosing is based on the effectiveness and tolerability of the patient's current regimen and one dosage recommendation is as follows:

- Take SYNJARDY twice daily with meals; with gradual dose escalation to reduce the gastrointestinal side effects due to metformin.

For further dosage and administration details, please refer to the Prescribing Information for Synjardy.

The recommended dosage of SYNJARDY XR is as follows:

- Take SYNJARDY XR orally once daily with a meal in the morning, based on the effectiveness and tolerability of the patient's current regimen.

For further dosage and administration details, please refer to the Prescribing Information for Synjardy XR.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

SGLT-2 INHIBITOR COMBINATION (MICHIGAN MEDICAID)

The recommended dosage of SEGLUROMET is as follows:

- Take SEGLUROMET twice daily with meals; with gradual dose escalation to reduce the gastrointestinal side effects due to metformin.

For further dosage and administration details, please refer to the Prescribing Information for Segluromet.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Hypersensitivity to canagliflozin or any component of the formulation
- Severe renal impairment (eGFR < 30ml/minute/1.73m²)
- End-stage renal disease
- The patient is on dialysis
- In addition, therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy
- The patient demonstrates no clinically significant improvement in condition after initiation of drug therapy

REFERENCES

- Invokamet [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; June 2018.
- Invokamet XR [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; September 2018.
- Synjardy [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; December 2017.
- Synjardy XR [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; December 2017.
- Segluromet [Prescribing Information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; December 2017.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

SUMATRIPTAN SUCCINATE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
SUMATRIPTAN SUCCINATE	IMITREX		24708 26666 26667 50740 50741 50742 50744	

This drug requires a written request for prior authorization.

INITIAL CRITERIA:

The guideline named **SUMATRIPTAN (Imitrex)** requires the diagnosis of migraines. In addition, all of the following criteria must be met:

- The patient is 18 years of age or older
- The requested medication is prescribed by or in consultation with a neurologist or pain management specialist
- The patient has documentation (e.g. labs, medical record, special studies and/or physician attestation) of **ALL** the following:
 - The patient has migraine induced vomiting
 - The patient has had a previous failure or intolerance to at least **ONE** formulary preferred alternative triptan tablet formulation: sumatriptan, naratriptan, rizatriptan
 - The patient has had a previous failure or intolerance to the formulary preferred alternative product: orally disintegrating rizatriptan tablet

RENEWAL CRITERIA:

The guideline named **SUMATRIPTAN (Imitrex)** requires the patient to have demonstrated efficacy as documented by an improvement in symptom management after initial therapy with Imitrex.

RATIONALE

To ensure appropriate use of sumatriptan (Imitrex) is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

IMITREX INJECTION is indicated in adults for the acute treatment of (1) migraine, with or without aura and (2) cluster headache.

Limitation of Use:

- Use only if a clear diagnosis of migraine or cluster headache has been established. If the patient has no response to the first migraine or cluster headache attack treated with Imitrex injection, reconsider the diagnosis before administering further Imitrex injection treatments.
- Imitrex injection is not indicated for the prevention of migraine or cluster headache attacks.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

SUMATRIPTAN SUCCINATE (MICHIGAN MEDICAID)

IMITREX NASAL SPRAY is indicated in adults for the acute treatment of migraine, with or without aura.

Limitation of Use:

- Use only if a clear diagnosis of migraine headache has been established. If the patient has no response to the first migraine attack treated with Imitrex nasal, reconsider the diagnosis of migraine before administering further Imitrex nasal treatments.
- Imitrex nasal is not indicated for the prevention of migraine attacks.
- Safety and effectiveness of Imitrex nasal spray have not been established for cluster headache.

DOSAGE AND ADMINISTRATION

IMITREX INJECTION for the acute treatment of migraine or cluster headache is 6mg subcutaneously. For the treatment of migraine, if side effects are dose limiting, lower doses (e.g. 1mg to 5mg) may be used. For the treatment of cluster headache, the efficacy of lower doses has not been established. The maximum cumulative dose that may be given in 24 hours is 12mg, two 6mg injections separated by at least 1 hour.

IMITREX NASAL SPRAY for the acute treatment of migraine is 5mg, 10mg or 20mg. If the migraine has not resolved by 2 hours after taking Imitrex nasal spray, or returns after a transient improvement, 1 additional dose may be administered at least two hours after the first dose. The maximum daily dose is 40mg in a 24-hour period. The safety of treating an average of more than 4 headaches in a 30 day period has not been established.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- History, symptoms, or signs of ischemic cardiac disease, peripheral vascular disease, uncontrolled hypertension
- The patient is using the requested drug within 24 hours of ergot-type drugs or within 2 weeks of discontinuing MAOIs
- Basilar headaches or hemiplegic migraine
- Hypersensitivity to sumatriptan or any of its components
- Patients with severe hepatic impairment
 - Hepatic impairment may cause unpredictable increases in the bioavailability of orally administered sumatriptan. Do not exceed 50mg/dose orally. Hepatic impairment does not significantly affect intranasal or subcutaneous hepatic impairment.
- Therapy may be discontinued if the patient is noncompliant with medical or pharmacological therapy **OR** demonstrates clinically significant improvement in condition after initiation of drug therapy
 - The patient has a poor response to treatment as evidenced by physical findings and/or clinical symptoms following the initial 3 months of approval coverage
 - The patient experiences intolerable adverse effects or drug toxicity

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

SUMATRIPTAN SUCCINATE (MICHIGAN MEDICAID)

REFERENCES

- Imitrex Injection [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline LLC.; July 2018.
- Imitrex Nasal Spray [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline LLC.; December 2017.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

TACROLIMUS OINTMENT (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
TACROLIMUS	PROTOPIC		12289 12302	

This drug requires a written request for prior authorization.

INITIAL CRITERIA:

The guideline named **TACROLIMUS (Protopic)** requires a diagnosis of atopic dermatitis. In addition, ONE of the following criteria must be met as documented by labs, medical record, special studies and/or physician attestation:

- The patient has had a trial, failure or contraindication of two topical corticosteroids OR
- There is a clinical reason why treatment with topical corticosteroids are not appropriate, including but not limited to:
 - Previous inadequate response
 - Skin atrophy OR
 - Use on an area of the body at high risk for skin atrophy, such as the face or skin folds

RENEWAL CRITERIA:

The guideline named **TACROLIMUS (Protopic)** requires a diagnosis of atopic dermatitis. In addition, BOTH of the following criteria must be met as documented by labs, medical record, special studies and/or physician attestation:

- The patient has met the initial criteria
- The prescriber deems a continued need for tacrolimus ointment

RATIONALE

To ensure appropriate use of Protopic is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

PROTOPIC ointment is indicated as second-line therapy for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children who have failure to respond adequately to other topical prescription treatments for atopic dermatitis, or when those treatments are not advisable. Both Protopic 0.03% and 0.1% ointment is indicated in adults, but only the 0.03% strength is indicated for children aged 2 to 15 years of age. Protopic ointment is not indicated for children younger than 2 years of age.

DOSAGE AND ADMINISTRATION

PROTOPIC 0.03% and 0.1% ointment for adults, and only the 0.03% strength for children aged 2 to 15 years of age have the following dosing recommendation:

- Apply a thin layer of Protopic ointment to the affected skin twice daily. The minimum amount should be rubbed in gently and completely to control signs and symptoms of atopic dermatitis. Stop using when signs and symptoms of atopic dermatitis resolve.
- If signs and symptoms (e.g. itch, rash, and redness) do not improve within 6 weeks, patients should be re-examined by their healthcare provider to confirm the diagnosis of atopic dermatitis.
- Continuous long-term use of topical calcineurin inhibitors, including Protopic ointment should be avoided, and application should be limited to areas of involvement with atopic dermatitis.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

TACROLIMUS OINTMENT (MICHIGAN MEDICAID)

- The esafety of PROTOPIC Ointment under occlusion, which may promote systemic exposure, has not been evaluated. PROTOPIC Ointment should not be used with occlusive dressings.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- When above criteria are not met
- Tacrolimus 0.1% ointment in children less than 16 years of age
- Concurrent therapy with Elidel
- noncompliant with medical or pharmacologic therapy
- No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

REFERENCES

- Protopic [Prescribing Information]. Madison, NJ: Leo Pharma Inc.; October 2018.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

TENOFOVIR ALAFENAMIDE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
TENOFOVIR ALAFENAMIDE	VEMLIDY	43907		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **TENOFOVIR ALAFENAMIDE (Vemlidy)** requires a diagnosis of Chronic Hepatitis B Infection. In addition, the following criteria must be met:

- The patient is 18 years of age or older
- The requested medication is prescribed by or in consultation with a hepatologist, gastroenterologist or infectious disease specialist
- There is documentation (e.g. labs, medical record, special studies and/or physician attestation) of **ALL** the following:
 - Diagnosis of Chronic Hepatitis B infection with compensated liver disease
 - Negative HIV test result (HIV testing: HIV antibody testing should be offered to all HBV infected patients prior to treatment initiation)
 - The patient has had a failure of entecavir, at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced
 - HBV DNA test every 3 months until undetectable for at least two consecutive visits, at which point the frequency may be decreased to every 6 months
 - Aminotransferase test every 3 months (the frequency can be decreased to every 6 months in patients with an undetectable HBV DNA or normalized ALT)
 - HBeAg and antibody to HBeAg (anti-HBe) tests every 6 months in patients who are HBeAg-positive to determine if seroconversion has occurred. If HBeAg seroconversion has occurred, repeat the HBeAg to confirm the result.
 - Yearly HBsAg test
 - Creatinine and phosphate test every 6 months

RENEWAL CRITERIA:

The guideline named **TENOFOVIR ALAFENAMIDE (Vemlidy)** requires a diagnosis of Chronic Hepatitis B Infection. In addition, the following criteria must be met as documented by e.g. labs, medical record, special studies and/or physician attestation:

- HBV DNA every 3 months until undetectable for at least 2 consecutive visits, at which point the frequency may be decreased to every 6 months
- Aminotransferase test every 3 months (the frequency can be decreased to every 6 months in patients with an undetectable HBV DNA or normalized ALT)
- HBeAg and antibody to HBeAg (anti-HBe) test every 6 months in patients who are HBeAg-positive to determine if seroconversion has occurred. If HBeAg seroconversion has occurred, repeat the HBeAg to confirm the result
- Yearly HBsAg test
- Creatinine and phosphate test every 6 months

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

TENOFOVIR ALAFENAMIDE (MICHIGAN MEDICAID)

RATIONALE

To ensure appropriate use of tenofovir alafenamide (Vemlidy) is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

VEMLIDY is indicated for the treatment of Chronic Hepatitis B virus (HBV) infection in adults with compensated liver disease.

DOSAGE AND ADMINISTRATION

- The recommended Vemlidy dosage is one (25mg) tablet taken orally once daily with food.
- Prior to initiation of Vemlidy, patients should be tested for HIV-1 infection, as Vemlidy alone should not be used in patients with HIV-1 infection.
- Prior to or when initiating Vemlidy, and during treatment, assess serum creatinine, estimated creatinine clearance, urine glucose and urine protein in all adult patients.
- In patients with chronic kidney disease, also assess serum phosphorus.
- No dosage adjustment is required in patients with mild, moderate, or severe renal impairment. (Vemlidy is not recommended in patients with end stage renal disease.)
- No dosage adjustment is required in patients with mild hepatic impairment (Child-Pugh A). (Vemlidy is not recommended in patients with decompensated (Child-Pugh B or C) hepatic impairment).

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- HIV and HBV coinfection: Should not be used as a single agent for the treatment of HIV due to resistance development risk.
- If HIV positive - provide further justification.
- For females: There have been no data reported to the antiretroviral registry related to the use of this drug in pregnancy. The Health and Human Services (HHS) Perinatal HIV Guidelines note data are insufficient to recommend tenofovir alafenamide for initial therapy in antiretroviral- naive pregnant women. Tenofovir disoproxil fumarate (Viread) preferred in pregnant women.

FDA APPROVED INDICATIONS (CONTINUED)

- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.
- Use is not recommended in those with CrCl < 15ml/minute or if Child-Pugh class B or C

REFERENCES

- Vemlidy [Prescribing Information]. Forester City, CA: Gilead Sciences, Inc.; July 2018.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

TERIPARATIDE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
TERIPARATIDE	FORTEO	24700		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA:

The guideline named **TERIPARATIDE (Forteo)** requires a diagnosis of osteoporosis in postmenopausal women, primary or hypogonadal osteoporosis in men, corticosteroid induced osteoporosis, or hypoparathyroidism. In addition, the following criteria must be met:

For the diagnosis of osteoporosis in postmenopausal women, approval requires:

- The patient is 18 years of age or older
- The requested medication is intended for the treatment of osteoporosis
- There is documentation (e.g., labs, medical records, special studies and/or physician attestation) of **ALL** of the following:
 - A baseline T-score less than or equal to -3 with a previous low impact fracture
 - The patient has failed Tymlos (abaloparatide)
 - The patient has failed despite compliance for at least 2 years, an intolerance or contraindication to an oral bisphosphonate
 - The patient has failed or has an intolerance to a compliant regimen of at least 12 months of zoledronic acid (generic Reclast)

For the diagnosis of primary or hypogonadal osteoporosis in men, approval requires:

- The patient is 18 years of age or older
- The requested medication is intended for the treatment of osteoporosis
- There is documentation (e.g., labs, medical records, special studies and/or physician attestation) of **ALL** of the following:
 - A baseline T-score less than or equal to -3 with a previous low impact fracture
 - The patient has failed despite compliance for at least 2 years, an intolerance or contraindication to an oral bisphosphonate
 - The patient has failed or has an intolerance to a compliant regimen of at least 12 months of zoledronic acid (generic Reclast)

For the diagnosis of corticosteroid induced osteoporosis, approval requires:

- The patient is 18 years of age or older
- The requested medication is intended for the treatment of osteoporosis
- There is documentation (e.g., labs, medical records, special studies and/or physician attestation) of **ALL** of the following:
 - A baseline T-score less than or equal to -1
 - The patient has failed despite compliance for at least 2 years, an intolerance or contraindication to an oral bisphosphonate
 - The patient has failed or had an intolerance to a compliant regimen of at least 12 months of zoledronic acid (generic Reclast)

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

TERIPARATIDE (MICHIGAN MEDICAID)

INITIAL CRITERIA (CONTINUED)

For the diagnosis of hypoparathyroidism, approval requires:

- The patient is 18 years of age or older
- The requested medication is intended for the treatment of hypoparathyroidism
- There is documentation (e.g., labs, medical records, special studies and/or physician attestation) of **BOTH** of the following:
 - Parathyroid hormone level (PTH) checked to rule out hyperparathyroidism
 - The patient has had a trial and failure of or intolerance to a compliant regimen of at least 2 months of a formulary medication used to treat hypoparathyroidism (e.g., Calcijex, Rocaltrol, ergocalciferol)

[NOTE: Failure is defined by new fracture while on treatment or reduction in BMD per recent DEXA scan. If member has a new fracture while on a bisphosphonate, a trial of only one bisphosphonate (PO/IV) is required.]

RENEWAL CRITERIA:

The guideline named **TERIPARATIDE (Forteo)** requires a diagnosis of osteoporosis in postmenopausal women, primary or hypogonadal osteoporosis in men, corticosteroid induced osteoporosis, or hypoparathyroidism. In addition, the following criteria must be met:

For the diagnosis of osteoporosis in postmenopausal women, primary or hypogonadal osteoporosis in men or corticosteroid induced osteoporosis, approval requires:

- Total duration of parathyroid hormone (e.g., Forteo, Tymlos) therapy has not exceeded a total of 24 months during the patient's lifetime
- The patient is responding to Forteo treatment with evidence of maintenance or improved T-score on DEXA scan

For the diagnosis of hypoparathyroidism, approval requires:

- There is documentation (e.g., labs, medical record, special studies and/or physician attestation) that the patient is tolerating and responding to treatment with Forteo.

RATIONALE

To ensure appropriate use of Forteo is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

Forteo is a recombinant human parathyroid hormone analog indicated for:

- For the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Forteo reduces the risk of vertebral and nonvertebral fractures.
- To increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.
- For the treatment of men and women with osteoporosis associated with sustained systemic corticosteroid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

CONTINUED ON NEXT PAGE

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

TERIPARATIDE (MICHIGAN MEDICAID)

OFF-LABEL INDICATIONS

- Treatment of hypoparathyroidism

DOSAGE AND ADMINISTRATION

The recommended dose of Forteo is 20 mcg subcutaneously once a day. Use for more than 2 years during a patient's lifetime is not recommended.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.
- See other special considerations.

OTHER SPECIAL CONSIDERATIONS

- **Box Warning:**
 - **Potential risk of osteosarcoma:** In male and female rats, teriparatide caused an increase in the incidence of osteosarcoma (a malignant bone tumor) that was dependent on dose and treatment duration. The effect was observed at systemic exposures to teriparatide ranging from 3 to 60 times the exposure in humans given a 20 mcg dose. Because of the uncertain relevance of the rat osteosarcoma finding to humans, prescribe teriparatide only to patients for whom the potential benefits are considered to outweigh the potential risk. Teriparatide should not be prescribed for patients who are at increased baseline risk for osteosarcoma (e.g., those with Paget disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, patients with prior external beam or implant radiation therapy involving the skeleton).

REFERENCES

- Forteo [Prescribing Information]. Indianapolis, IN. Eli Lilly and Company; April 2017.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_5228_28_7.pdf [Accessed October 1, 2018].
- Cosman F, de Beur SJ, LeBoff MS, et al. Clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int* 2014; 25:2359.
- Amir Qaseem, Mary Ann Forciea, Robert M. McLean, Thomas D. Denberg. Treatment of Low Bone Density or Osteoporosis to Prevent Fractures in Men and Women: A Clinical Practice Guideline Update From the American College of Physicians. *Ann Intern Med.* 2017;166:818–839. doi: 10.7326/M15-1361
- AACE/ACE Postmenopausal Osteoporosis CPG, *Endocr Pract.* 2016;22(Suppl 4).

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

TIOTROPIUM BROMIDE (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
TIOTROPIUM BROMIDE	SPIRIVA HANDIHALER		17853	

This drug requires a written request for NON-FORMULARY exception.

GUIDELINES FOR USE

INITIAL CRITERIA:

The non-formulary exception guideline named **TIOTROPIUM BROMIDE HANDIHALER (SPIRIVA HANDIHALER)** requires a diagnosis of Chronic Obstructive Pulmonary Disease (COPD). In addition, the following criteria must be met:

- There is documentation (labs, medical record, special studies and/or physician attestation) for trial, failure, or contraindication to all formulary agents: Incruse Ellipta

RENEWAL CRITERIA:

The non-formulary exception guideline named **TIOTROPIUM BROMIDE HANDIHALER (SPIRIVA HANDIHALER)** requires a diagnosis of Chronic Obstructive Pulmonary Disease (COPD). In addition, there must be documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of ALL of the following:

- The patient currently meets ALL initial coverage criteria
- The patient is adherent to prescribed therapy
- Documentation of stabilization or improvement of symptoms.

FDA APPROVED INDICATIONS

Indicated for the long term, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), and for reducing COPD exacerbations.

DOSAGE AND ADMINISTRATION

The recommended dosage of Spiriva Handihaler for the treatment of COPD is two inhalations of the powder contents of a single Spiriva capsule once.

REFERENCES

- Spiriva Handihaler [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; Feb 2018.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

TIOTROPIUM BROMIDE/OLODATEROL (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
TIOTROPIUM BROMIDE /OLODATEROL HCL	STIOLTO RESPIMAT		38687	

This drug requires a written request for NON-FORMULARY exception.

GUIDELINES FOR USE

INITIAL CRITERIA:

The non-formulary exception guideline named **TIOTROPIUM BROMIDE/OLODATEROL (STIOLTO RESPIMAT)** requires a diagnosis of Chronic Obstructive Pulmonary Disease (COPD). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- There is documentation (labs, medical record, special studies and/or physician attestation) for trial, failure, or contraindication to formulary agents: Combivent **OR** Incruse Ellipta **AND** Serevent

RENEWAL CRITERIA:

The non-formulary exception guideline named **TIOTROPIUM BROMIDE/OLODATEROL (STIOLTO RESPIMAT)** requires a diagnosis of Chronic Obstructive Pulmonary Disease (COPD). In addition, there must be documentation (e.g. Labs, Medical Record, Special Studies and/or Physician Attestation) of ALL of the following:

- The patient currently meets ALL initial coverage criteria
- The patient is adherent to prescribed therapy
- Documentation of stabilization or improvement of symptoms.

FDA APPROVED INDICATIONS

Indicated for the long term, maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

DOSAGE AND ADMINISTRATION

The recommended dosage of Stiolto Respimat for the treatment of COPD is two inhalations once daily at the same time of day.

REFERENCES

- Stiolto Respimat [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; Oct 2018.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

TOBRAMYCIN INHALATION SOLUTION (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
TOBRAMYCIN INHALATION SOLUTION	TOBI-GENERIC, TOBI PODHALER, BETHKIS, KITABIS PAK		16122 37569 30025 34461 61551	

This drug requires a written request for prior authorization.

INITIAL CRITERIA FOR TOBRAMYCIN INHALATION SOLUTION (Tobi-generic, Kitabis Pak and Bethkis) :

The guideline named **TOBRAMYCIN INHALATION SOLUTION (Tobi-generic, Kitabis Pak and Bethkis)** require a diagnosis of Cystic Fibrosis (CF). In addition, the following must criteria be met:

- The patient is 6 years of age or older
- The requested medication is being prescribed by or in consultation with a pediatrician, pulmonologist or infectious disease specialist
- Documentation (e.g. labs, medical record, special studies and/or physician attestation) of suspected or confirmed diagnosis of *Pseudomonas aeruginosa* lung infection

INITIAL CRITERIA FOR TOBRAMYCIN INHALATION SOLUTION (Tobi Podhaler) :

The guideline named **TOBRAMYCIN INHALATION SOLUTION (Tobi Podhaler)** requires a diagnosis of Cystic Fibrosis (CF). In addition, the following criteria must be met:

- The patient is 6 years of age or older
- The requested medication is being prescribed by or in consultation with a pediatrician, pulmonologist or infectious disease specialist
- Documentation (e.g. labs, medical record, special studies and/or physician attestation) of BOTH of the following:
 - Suspected or confirmed diagnosis of *Pseudomonas aeruginosa* lung infection
 - The patient has tried and failed tobramycin inhalation solution (generic TOBI®)

RENEWAL CRITERIA:

The guideline named **TOBRAMYCIN INHALATION SOLUTION (Tobi-generic, Kitabis Pak, Bethkis and Tobi Podhaler)** requires a diagnosis of Cystic Fibrosis (CF). In addition, documentation (e.g. labs, medical record, special studies and/or physician attestation) that the following criterion has been met is required:

- Confirmation that the patient continues to have a beneficial response to therapy as assessed and documented by the patients's provider

RATIONALE

To ensure appropriate use of tobramycin inhalation solution (Tobi-generic, Kitabis Pak, Bethkis and Tobi Podhaler) is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

TOBI- GENERIC SOLUTION, BETHKIS, KITABIS PAK and TOBI PODHALER are all indicated for for the management of cystic fibrosis patients with *Pseudomonas aeruginosa*.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

TOBRAMYCIN INHALATION SOLUTION (MICHIGAN MEDICAID)

Limitation of Use

Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with FEV₁ <25% or >75% predicted, or patients colonized with *Burkholderia cepacia*.

DOSAGE AND ADMINISTRATION

TOBI- GENERIC SOLUTION and KITABIS PAK

The recommended dosage for both adults and pediatric patients 6 years of age and older is 1 single-use ampule (300 mg) administered BID for 28 days. Dosage is not adjusted by weight. All patients should be administered 300 mg BID. The doses should be taken as close to 12 hours apart as possible; they should not be taken less than 6 hours apart.

BETHKIS

The recommended dosage for patients 6 years of age and older is to administer one single-use ampule (300 mg/4 mL) twice daily by oral inhalation in repeated cycles of 28 days on drug, followed by 28 days off drug. The doses should be taken as close to 12 hours apart as possible and not less than 6 hours apart.

TOBI PODHALER

The recommended dosage of TOBI Podhaler for both adults and pediatric patients 6 years of age and older is the inhalation of the contents of four 28 mg TOBI Podhaler capsules twice-daily for 28 days using the Podhaler device. For further dosage and administration instructions, please refer to the Prescribing Information for TOBI Podhaler.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Patient is noncompliant with medical or pharmacologic therapy
- No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy
- Allergy to tobramycin or other aminoglycosides

REFERENCES

- Tobramycin inhalation solution [Prescribing Information]. Lake Forest, IL. Akorn, Inc.; December 2017.
- Kitabis Pak [Prescribing Information]. Woodstock, IL. Catalent Pharma Solutions, LLC; March 2018.
- Bethkis [Prescribing Information]. Woodstock, IL. Chiesi USA, Inc./Catalent Pharma Solutions, LLC; August 2018.
- Tobi Podhaler [Prescribing Information]. East Hanover, NJ. Novartis; December 2016.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_5228_28_7.pdf [Accessed October 1, 2018].

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

VALGANCICLOVIR (MICHIGAN MEDICAID)

Generic	Brand	HICL	GCN	Exception/Other
VALGANCICLOVIR	VALCYTE		13088	

This drug requires a written request for prior authorization.

INITIAL CRITERIA:

The guideline named **VALGANCICLOVIR (Valcyte)** requires a diagnosis of Cytomegalovirus (CMV) retinitis in HIV-infected patient, or that Valcyte is being used for prophylaxis for adult patients at high risk of CMV disease following transplantation of the heart, kidney-pancreas, or kidney OR for prophylaxis in pediatric patients also at high risk for CMV disease following kidney or heart transplant. In addition, the following must be met:

For cytomegalovirus (CMV) reinitis in HIV-infected patient, approval requires:

- The patient is 18 years of age or older
- Documentation (e.g. labs, medical record, special studies and/or physician attestation) that the requested medication will be used in combination with Vitrasert (ganciclovir intraocular implant)

For prophylaxis in adult patients at high risk of CMV disease following transplantation of the heart, kidney-pancreas, or kidney OR for prophylaxis in pediatric patients also at high risk for CMV disease following kidney or heart transplant, no extra criteria is required for approval.

RENEWAL CRITERIA:

The guideline named **VALGANCICLOVIR (Valcyte)** requires for valganciclovir to be used in the treatment of patients with a diagnosis of Cytomegalovirus (CMV) retinitis and HIV-infection, OR that valganciclovir is being used for prophylaxis in adult patients at high risk of CMV disease following transplantation of the heart, kidney-pancreas, or kidney, OR that valganciclovir is being used for prophylaxis in pediatric patients at high risk for CMV disease following kidney or heart transplant. In addition, the following criterion must be met:

- The patient is tolerating and responding to treatment

RATIONALE

To ensure appropriate use of valganciclovir (Valcyte) is consistent with FDA-approved indications and Michigan Medicaid requirements.

FDA APPROVED INDICATIONS

VALCYTE is approved in adult patients for:

- 1) Treatment of Cytomegalovirus (CMV) Retinitis in patients with acquired immunodeficiency syndrome (AIDS)
- 2) For the prevention of CMV disease in kidney, heart, and kidney-pancrease transplant patients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-])

VALCYTE is approved in pediatric patients for the prevention of CMV disease in kidney transplant patients (4 months to 16 years of age) and heart transplant patients (1 month to 16 years of age) at high risk.

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**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

VALGANCICLOVIR (MICHIGAN MEDICAID)

DOSAGE AND ADMINISTRATION

The following are VALCYTE dosing recommendation in adult patients:

1) For the treatment of Cytomegalovirus (CMV) Retinitis in patients with acquired immunodeficiency syndrome (AIDS)

- Induction: 900mg (two 450mg tablets) taken orally twice daily for 21 days
- Maintenance: 900mg (two 450mg tablets) taken orally once daily

2) For the prevention of CMV disease in kidney, heart, and kidney-pancrease transplant patients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-])

- For heart or kidney-pancreas transplant, the recommended dosage is 900mg (two 450mg tablets) taken orally once daily, starting within 10 days of transplantation until 100 days post-transplantation
- For kidney transplant, the recommended dosage is 900mg (two 450mg tablets) taken orally once daily, starting within 10 days of transplantation until 200 days post-transplantation

The following are VALCYTE dosing recommendation in pediatric patients:

1) For the prevention of CMV disease in kidney transplant patients (4 months to 16 years of age), the recommended once daily mg dose ($7 \times \text{BSA} \times \text{CrCl}$) should start within 10 days of post-transplantation until 200 days post-transplantation.

2) For the prevention of CMV disease in heart transplant patients (1 month to 16 years of age), the recommended once daily mg dose ($7 \times \text{BSA} \times \text{CrCl}$) should start within 10 days of post-transplantation until 100 days post-transplantation.

All calculated doses should be rounded to the nearest 10 mg increment for the actual deliverable dose. If the calculated dose exceeds 900 mg, a maximum dose of 900 mg should be administered.

For further dosing details please, refer to the Prescribing Information for Valcyte.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION

- Hypersensitivity to valganciclovir or ganciclovir
- The patient is noncompliant with medical or pharmacologic therapy
- The patient does not demonstrate a clinically significant improvement in condition after initiation of drug therapy

REFERENCES

- Valcyte [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; August 2018.
- Michigan Health Plan Common Formulary Prior Authorization Criteria. Available at: https://www.michigan.gov/documents/mdhhs/MCO_Common_Formulary_PA_Criteria_FINAL_522828_7.pdf [Accessed October 1, 2018].

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MCLAREN HEALTH PLAN MEDICAID PRIOR AUTHORIZATION GUIDELINES

INDEX

	CLOBETASOL PROPIONATE 33
	CYCLOPHOSPHAMIDE 141
A	D
ABALOPARATIDE 2	DALFAMPRIDINE 34
ABIRATERONE ACET, SUBMICRONIZED 141	DAPAGLIFLOZIN PROPANEDIOL 36
ABIRATERONE ACETATE 141	DARAPRIM 171
ACITRETIN 4	DARBEPOETINALFA 58
ADALIMUMAB 6	DARIFENACIN HYDROBROMIDE 144
ADCIRCA 161	DDAVP STIMATE 37
ADEMPAS 153	DEPO-PROVERA SYRINGE 130
ADMELOG SOLOSTAR 13	DESMOPRESSIN ACETATE 37
ADVAIR DISKUS 78	DICLOFENAC 39
ADVAIR HFA 79	DIMETHYL FUMARATE 41
AFINITOR 141	DORNASE ALPHA 45
AFINITOR DISPERZ 141	DOVONEX 30
ALDARA 105	DRONABINOL 50
ALISKIREN 14	DULAGLUTIDE 28
ALKERAN 141	DULERA 133
AMBRISENTAN 146	DURAGESIC 70
AMITIZA 125	
AMPYRA 34	E
APALUTAMIDE 141	EFUDEX 76
APIXABAN 17	ELIDEL 169
APREMILAST 20	ELIQUIS 17
ARANESP 58	ELMIRON 168
ASTHMA AND COPD AGENTS (SYMBICORT) 27	EMCYT 141
ATOVAQUONE 22	EMPAGLIFLOZIN 182
AVONEX 112	EMPAGLIFLOZIN/METFORMIN HCL 184
AVONEX ADMINISTRATION PACK 112	ENABLEX 144
AVONEX PEN 112	ENASIDENIB MESYLATE 141
AZTREONAM 23	ENBREL 63
	ENCORAFENIB 141
B	ENDARI 120
BENZNIDAZOLE 25	ENOXAPARIN 53
BETHKIS 199	ENTRESTO 178
BEXAROTENE 141	ENZALUTAMIDE 141
BICALUTAMIDE 141	EPOETIN ALFA 60
BOSENTAN 149	EPOGEN 60
BRAFTOVI 141	ERIVEDGE 142
BRAND MEDICALLY NECESSARY 26	ERLEADA 141
BUDESONIDE/ FORMOTEROL FUMARATE 27	ERTUGLIFLOZIN 182
BUSULFAN 141	ERTUGLIFLOZIN/METFORMIN HCL 184
BYDUREON BCISE 28	ESTRAMUSTINE PHOSPHATE SODIUM 141
BYDUREON PEN 28	ETANERCEPT 63
BYETTA 28	ETOPOSIDE 141
	EULEXIN 141
C	EVEROLIMUS 141
CALCIPOTRIENE 30	EXENATIDE 28
CANAGLIFLOZIN 182	EXENATIDE MICROSPHERES 28
CANAGLIFLOZIN/METFORMIN HCL 184	EZETIMIBE 66
CAPECITABINE 141	
CARAC 76	F
CASODEX 141	FARESTON 142
CAYSTON 23	FARXIGA 36
CHLORAMBUCIL 141	FARYDAK 141
CINACALCET 31	
CLARAVIS 115	

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

FEBUXOSTAT	68
FENTANYL TRANSDERMAL PATCH	70
FESOTERODINE FUMARATE	144
FILGRASTIM.....	80
FILGRASTIM-SNDZ.....	80
FINGOLIMOD	73
FLUOROURACIL CREAM	76
FLUTAMIDE.....	141
FLUTICASONE/ SALMETEROL DISKUS.....	78
FLUTICASONE/ SALMETEROL HFA.....	79
FORTEO	194
FOSRENOL CHEWABLE	117

G

GILENYA.....	73
GLATIRAMER ACETATE	90
GLATOPA	90
GLEOSTINE.....	141
GLP-1 ANALOGS-BYETTA, BYDUREON, TRULICITY.28, 29	
GRANIX	80

H

HUMALOG CARTRIDGE	134
HUMALOG JUNIOR KWIKPEN	134
HUMALOG KWIK U-100	134
HUMALOG VIAL	134
HUMIRA	6
HUMULIN R U-500.....	110
HYCAMTIN	142

I

IDHIFA	141
IMIQUIMOD	105
IMITREX.....	187
INCRELEX	127
INSULIN ASPART	134
INSULIN DEGLUDEC	107
INSULIN DETEMIR	108
INSULIN GLARGINE.....	109
INSULIN LISPRO	134
INSULIN LISPRO - ADMELOG SOLOSTAR	13
INSULIN REGULAR, HUMAN U-500.....	110
INTERFERON ALFA-2B, RECOMB.....	141
INTERFERON BETA 1A	112
INTERFERON BETA-1A/ALBUMIN	112
INTRON A	141
INVOKAMET	184
INVOKAMET XR	184
INVOKANA.....	182
ISOTRETINOIN.....	115
IVOSIDENIB.....	141

J

JAKAFI	141
JANUMET	47
JANUMET XR	47

JANUVIA.....	47
JARDIANCE.....	182
JENTADUETO	47

K

KITABIS PAK	199
-------------------	-----

L

LANTHANUM CARBONATE.....	117
LANTUS	109
LANTUS SOLOSTAR	109
LARIAM.....	131
LENALIDOMIDE	141
LETAIRIS	146
LEUKERAN.....	141
LEUPROLIDE ACETATE.....	141
LEVALBUTEROL HCL.....	119
LEVEMIR	108
LEVEMIR FLEXPEN	108
LEVEMIR FLEXTOUCH.....	108
L-GLUTAMINE	120
LINAGLIPTIN	47
LINAGLIPTIN-METFORMIN	47
LINEZOLID	122
LIRAGLUTIDE.....	92
LOMUSTINE	141
LONSURF	142
LOVAZA	139
LOVENOX.....	53
LUBIPROSTONE	125
LUPRON	141
LYSODREN	141

M

MARINOL.....	50
MATULANE.....	141
MECASERMIN.....	127
MEDROXYPROGESTERONE ACETATE	130
MEFLOQUINE	131
MELPHALAN	141
MEPRON	22
MESNA	141
MESNEX.....	141
METHOTREXATE.....	141
MIRABEGRON.....	144
MITOTANE	141
MOMETASONE/ FORMOTEROL.....	133
MYLERAN.....	141
MYRBETRIQ.....	144

N

NAPROSYN SUSPENSION	135
NAPROXEN SUSPENSION	135
NEUPOGEN.....	80
NILANDRON	141
NILUTAMIDE	141
NORDITROPIN FLEXPRO	96

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

NORDITROPIN NORDIFLEX.....	96
NOVOLOG CARTRIDGE.....	134
NOVOLOG FLEXPEN.....	134
NOVOLOG VIAL.....	134

O

OCTREOTIDE ACETATE.....	137
ODOMZO.....	141
OMEGA 3 ACID.....	139
ONCOLOGY AGENTS.....	141, 143
OTEZLA.....	20
OVERACTIVE BLADDER.....	144
OZEMPIC.....	92

P

PALIVIZUMAB.....	165
PANOBINOSTAT LACTATE.....	141
PENTOSAN POLYSULFATE.....	168
PIMECROLIMUS.....	169
POMALIDOMIDE.....	141
POMALYST.....	141
PROCARBAZINE HCL.....	141
PROCRIT.....	60
PROTOPIC.....	190
PULMOZYME.....	45
PYRIMETHAMINE.....	171

R

RANEXA.....	173
RANOLAZINE.....	173
REVELA, RENAGEL.....	180
REVATIO.....	157
REVLIMID.....	141
RIOCIGUAT.....	153
RIVAROXABAN.....	175
RUXOLITINIB PHOSPHATE.....	141

S

SACUBITRIL-VALSARTAN.....	178
SANDOSTATIN.....	137
SEGLUROMET.....	184
SEMIPLUTIDE.....	92
SENSIPAR.....	31
SEVELAMER.....	180
SGLT-2 INHIBITOR.....	182
SGLT-2 INHIBITOR COMBINATION.....	184, 185, 186
SILDENAFIL.....	157
SITAGLIPTIN.....	47
SITAGLIPTIN-METFORMIN.....	47
SITAGLIPTIN-METFORMIN XR.....	47
SOLARAZE.....	39
SOLIFENACIN SUCCINATE.....	144
SOMATROPIN.....	96
SONIDEGIB PHOSPHATE.....	141
SORIATANE.....	4
SPIRIVA HANDIHALER.....	197
STEGLATRO.....	182

STIOLTO RESPIMAT.....	198
SUMATRIPTAN SUCCINATE.....	187
SYMBICORT.....	27
SYNAGIS.....	165
SYNJARDY.....	184
SYNJARDY XR.....	184

T

TABLOID.....	142
TACROLIMUS.....	190
TADALAFIL.....	161
TARGRETIN.....	141
TBO-FILGRASTIM.....	80
TECFIDERA.....	41
TEKTURNA.....	14
TEMODAR.....	142
TEMOVATE.....	33
TEMOZOLOMIDE.....	142
TENOFOVIR ALAFENAMIDE.....	192
TERIPARATIDE.....	194
THALIDOMIDE.....	142
THALOMID.....	142
THIOGUANINE.....	142
TIBSOVO.....	141
TIOTROPIUM BROMIDE.....	197
TIOTROPIUM BROMIDE /OLODATEROL HCL.....	198
TOBI PODHALER.....	199
TOBI-GENERIC.....	199
TOBRAMYCIN INHALATION SOLUTION.....	199
TOPOTECAN HCL.....	142
TOREMIFENE CITRATE.....	142
TOUJEO MAX SOLOSTAR.....	109
TOUJEO SOLOSTAR.....	109
TOVIAZ.....	144
TRACLEER.....	149
TRADJENTA.....	47
TRESIBA.....	107
TRESIBA FLEXTOUCH.....	107
TRETINOIN.....	142
TRIFLURIDINE/TIPIRACIL HCL.....	142
TRULICITY.....	28
TYMLOS.....	2

U

ULORIC.....	68
-------------	----

V

VALCYTE.....	201
VALGANCICLOVIR.....	201
VEMLIDY.....	192
VEPESID.....	141
VESANOID.....	142
VESICARE.....	144
VICTOZA.....	92
VISMODEGIB.....	142
VORINOSTAT.....	142

**MCLAREN HEALTH PLAN MEDICAID
PRIOR AUTHORIZATION GUIDELINES**

X

XARELTO	175
XATMEP	141
XELODA	141
XOPENEX	119
XOPENEX CONCENTRATE	119
XTANDI	141

Y

YONSA	141
-------------	-----

Z

ZARXIO	80
ZETIA	66
ZOLINZA	142
ZYTIGA	141
ZYVOX	122