

Metreleptin (MYALEPT®)

Goal(s):

- Promote evidence-based standard of care in patients diagnosed with lipodystrophy due to leptin deficiency.
- Limit to populations in which metreleptin has been studied and approved by the Food and Drug Administration.

Length of Authorization:

- Up to 12 months

Requires PA:

- Metreleptin (pharmacy and physician administered claims)

Covered Populations: FFS patients

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request for a patient with a prior FFS approval for the requested drug?	Yes: Go to Renewal Criteria	No: Go to #3
3. Is this an FDA approved age and indication?	Yes: Go to #4	No: Pass to RPh. Deny; medical appropriateness
4. Does the patient have any of the following diagnoses: <ul style="list-style-type: none"> • Partial lipodystrophy • Non-alcoholic steatohepatitis (NASH) or metabolic dysfunction-associated steatohepatitis (MASH) • General obesity not associated with congenital leptin deficiency • HIV-related lipodystrophy or • Metabolic disease (diabetes, hypertriglyceridemia) without evidence of generalized lipodystrophy? 	Yes: Pass to RPh. Deny; medical appropriateness	No: Go to #5
5. Is the drug prescribed by an endocrinologist or a provider with experience in managing lipodystrophy due to leptin deficiency?	Yes: Go to #6	No: Pass to RPh. Deny; medical appropriateness

Approval Criteria

<p>6. Are there documented baseline assessments for all of the following within the past year:</p> <ul style="list-style-type: none"> • Serum leptin level • Hemoglobin A1C • Fasting triglycerides 	<p>Yes: Go to #7</p> <p>Document date and lab results_____</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>7. Does the patient have:</p> <ul style="list-style-type: none"> • Persistent hyperglycemia (HbA1c > 6.5%) despite dietary interventions AND • Persistent fasting hypertriglyceridemia (TG > 200 mg/dL) despite dietary interventions 	<p>Yes: Go to #8</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>8. Is the patient on maximally tolerated therapy for diagnosed diabetes and hypertriglyceridemia when applicable with the following medications:</p> <ul style="list-style-type: none"> • Optimized diabetes therapy (insulin, metformin, GLP-1 antagonist, or SGLT-2 inhibitor) at maximum tolerated dose for at least 6 months • Optimized therapy with at least 2 triglyceride-lowering agents (e.g., fibrates, statins) at maximum tolerated doses for at least 6 months • Or do they have documented age or co-morbidity contraindication to these medications 	<p>Yes: Approve for 6 months</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>

Renewal Criteria

<p>1. Is there documented evidence of adherence and tolerance to therapy based on claims history and provider assessment?</p>	<p>Yes: Go to #2</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>2. Has the provider re-evaluated the following baseline assessments based upon pre-existing diagnoses within the past 6 months?</p> <ul style="list-style-type: none"> • HbA1c • Serum triglycerides 	<p>Yes: Go to #3</p> <p>Document date and lab values_____</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>

Renewal Criteria

3. Has A1C reduced by at least 0.5% from baseline or have fasting triglycerides reduced by at 15%?

Yes: Approve for 12 months

No: Pass to RPh. Deny; medical appropriateness

*P&T/DUR Review: 4/26 (DM)
Implementation: 6/1/26*