

PHARMACY POLICY – 5.01.553


Myalept (metreleptin)

Effective Date: May 1, 2025
Last Revised: Apr. 21, 2025
Replaces: N/A

RELATED MEDICAL POLICIES:
None

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Introduction

Lipodystrophy is a condition in which there is little or no fat tissue in the body. If a person is born with the condition, it's known as congenital lipodystrophy. Acquired lipodystrophy refers to the condition when it's not inherited. Acquired lipodystrophy can arise because of medications, problems with the immune system, or for an unknown reason. A lack of body fat results in low levels of the hormone leptin. Leptin controls specific process in the body, and not having enough of this hormone can lead to other health problems, like too much fat in the blood and high blood sugar. Myalept is a drug that can be used in some cases to treat low levels of leptin. This policy describes when this drug may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Drug	Medical Necessity
Myalept (metreleptin) SC	<p>Myalept (metreleptin) may be considered medically necessary as an adjunct to diet to treat the complications of leptin deficiency in individuals with congenital or acquired lipodystrophy when the following criteria are met:</p> <ul style="list-style-type: none"> • The individual has a confirmed diagnosis of leptin deficiency <p>AND</p> <ul style="list-style-type: none"> • Documentation that Myalept (metreleptin) is being used along with a doctor-recommended diet for generalized lipodystrophy <p>AND</p> <ul style="list-style-type: none"> • Has one of the following metabolic abnormalities at baseline: <ul style="list-style-type: none"> ○ Diabetes mellitus and an HbA_{1c} ≥ 7% with optimized insulin therapy ○ Fasting triglyceride values of ≥ 250 mg/dL after treatment with two or more lipid lowering agents <p>AND</p> <ul style="list-style-type: none"> • Myalept (metreleptin) is prescribed by or in consultation with an endocrinologist <p>AND</p> <ul style="list-style-type: none"> • Dose prescribed is equal to or less than 10 mg once daily

Drug	Investigational
Myalept (metreleptin)	<p>Use of Myalept (metreleptin) for all other indications is considered investigational.</p> <p>The medications listed in this policy are subject to the product's US Food and Drug Administration (FDA) dosage and administration prescribing information.</p>

Length of Approval	
Approval	Criteria
Initial authorization	Non-formulary exception reviews and all other reviews for Myalept (metreleptin) may be approved up to 12 months.
Re-authorization criteria	Non-formulary exception reviews and all other reviews for Myalept (metreleptin) may be approved up to 12 months as long as the drug-specific coverage criteria are met, chart notes



Length of Approval

Approval	Criteria
	document that the individual is tolerating therapy, and there is a decrease in HbA _{1c} and/or fasting triglyceride levels from baseline.

Documentation Requirements

The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Office visit notes that contain the diagnosis, relevant history, physical evaluation, individual specific diet, prescribed dose, and documented metabolic abnormality

Coding

N/A

Related Information

Benefit Application

This drug is managed through the pharmacy benefit.

Evidence Review

Description

Disease Characteristics & Pathophysiology

Lipodystrophy is a group of clinically heterogeneous metabolic disorders that are either acquired or inherited and result in loss of adipose tissue. This leads to disruption of various



metabolic pathways. The disease is classified primarily based on 2 factors: whether it is genetic or acquired and whether fat loss is generalized or partial. Therefore, there are 4 major classifications:

- Congenital generalized lipodystrophy (CGL), also known as Berardinelli–Seip syndrome
- Familial partial lipodystrophy (FPL)
- Acquired generalized lipodystrophy (AGL)
- Acquired partial lipodystrophy (APL), also known as Barraquer–Simons syndrome

This general classification scheme is not inclusive of all lipodystrophies because rare lipodystrophies, such as mandibuloacral dysplasia, neonatal progeria, and atypical progeria, may not fit exactly into one of the 4 main subgroups. Further, one individual may fall into more than 1 main subgroups.

Many genetic mutations have been identified in congenital and familial lipodystrophies, such as AGPAT2, seipin, LMNA, PPAR γ , ZMPSTE24, and LMNB2. These mutations can follow autosomal recessive (AGPAT2, seipin) or autosomal dominant (LMNA) inheritance patterns. Acquired lipodystrophies can be autoimmune-associated. Individuals with CGL, AGL, and APL often present with metabolic abnormalities during childhood or adolescence, whereas those with FPL tend to present later in adolescence and adulthood.

Adipose tissue is an endocrinologically active tissue as it secretes multiple hormones (leptin and adiponectin) and cytokines. Leptin is a key regulator in energy homeostasis as well as fat and glucose metabolism. The relative leptin deficiency that occurs as a result of loss of adipose tissue has been implicated as a key pathogenic mechanism underlying lipodystrophy. Lipodystrophy is associated with deposition of fat in ectopic locations (e.g., liver and muscle) and metabolic abnormalities (e.g., insulin resistance, hypertriglyceridemia, and diabetes).

Common clinical complications and manifestations of lipodystrophy include:

- Insulin-resistant diabetes mellitus and resulting complications
- Severe hypertriglyceridemia, which may lead to acute pancreatitis
- Hepatic steatosis or steatohepatitis which may progress to cirrhosis
- Proteinuric nephropathies, which may lead to renal failure
- Severe cardiovascular complications, such as premature atherosclerotic disease and hypertrophic cardiomyopathy



- Reproductive and hormonal abnormalities in women
- Increased appetite leading to hyperphagia

Epidemiology and Risk Factors

Lipodystrophy is a rare disease. According to a 2004 review, approximately 800 cases of lipodystrophy (CGL, FPL, AGL, and APL, excluding HIV-related lipodystrophy) have been reported in the literature. Because of the rarity of the condition, epidemiologic data for this disease are not available.

Clinical Presentation

The clinical presentation of lipodystrophy varies by type of lipodystrophy and from individual-to-individual. Extreme loss of subcutaneous fat is apparent from birth in CGL, while it becomes apparent at puberty in individuals with FPL. In APL individuals, there is loss of fat from the face, neck, arms, and trunk, but legs are spared. In AGL individuals, there is generalized loss of fat associated with tender subcutaneous nodules along with autoimmune or other diseases. Affected individuals are predisposed to insulin resistance and its attendant complications, such as diabetes mellitus, dyslipidemia, hepatic steatosis, and acanthosis nigricans. Features of polycystic ovary syndrome that include hirsutism, oligoamenorrhea, and polycystic ovaries may develop in affected women. The impact of the disease on physical appearance can cause severe psychological distress in many individuals.

Diagnosis

Generalized lipodystrophies are easily detected clinically and are usually diagnosed by pediatricians because of the characteristic features from birth onwards. Partial lipodystrophies, on the other hand, are more difficult to recognize, only causing metabolic abnormalities later in life. Because many metabolic features of partial lipodystrophy resemble those of metabolic syndrome and/or type 2 diabetes mellitus, individuals with FPL are often misdiagnosed. The only clinical signs that are unique to such individuals are lipoatrophy and the onset of severe metabolic abnormalities.

The American Association of Clinical Endocrinologist has recently published a consensus statement for diagnosis of lipodystrophy. This consensus statement describes the clinical



approach for diagnosis of lipodystrophy. These statements only summarize certain clinical features that may arouse suspicion of lipodystrophy but are not definitive of a diagnosis.

American Association of Clinical Endocrinologist Criteria That Raise Clinical Suspicion of Lipodystrophy

Core clinical characteristic for lipodystrophy:

- Loss or absence of subcutaneous body fat in a partial or generalized fashion

Core clinical characteristic for Familial partial lipodystrophy:

- Loss of subcutaneous body fat, typically occurring around or shortly after puberty, occurring in the extremities and/or gluteal region with sparing of fat loss or accumulation of excess fat in the face and neck or intra-abdominal area

Supportive clinical characteristics for lipodystrophy:

- Presence of diabetes with evidence of severe insulin resistance
- Diabetes mellitus with requirement for high doses of insulin
- Ketosis-resistant diabetes
- Other evidence of severe insulin resistance
- Acanthosis nigricans
- PCOS or PCOS-like symptoms (hyperandrogenism, oligomenorrhea, and/or polycystic ovaries)
- Presence of hypertriglyceridemia
- Severe hypertriglyceridemia (≥ 500 mg/dL)
- Triglyceride levels that are nonresponsive to therapy and/or modifications to diet (≥ 250 mg/dL)
- History of pancreatitis associated with hypertriglyceridemia
- Evidence of hepatic steatosis or steatohepatitis



- Hepatomegaly and/or elevated transaminases in the absence of a known cause of liver disease (e.g., viral hepatitis) may be consistent with nonalcoholic fatty liver disease
- Radiographic evidence of hepatic steatosis (e.g., on ultrasound or computed tomography)
- Family history of similar physical appearance and/or history of fat loss
- Prominent muscularity and phlebomegaly (enlarged veins) in the extremities
- Disproportionate hyperphagia (cannot stop eating, waking up to eat, fighting for food)
- Secondary hypogonadism in a male or primary/secondary amenorrhea in a female individual

Therapeutic Options

The primary goal of treatment in individuals with lipodystrophies is to prevent morbidity and mortality as a result of diabetes mellitus, recurrent episodes of acute pancreatitis and cirrhosis.

Current treatment options for lipodystrophies include antidiabetic and lipid-lowering medications. These treatment options may address the metabolic abnormalities associated with lipodystrophy, but not the underlying pathophysiologic abnormalities. Further, these treatments are often rendered marginally effective by the severity of the abnormalities observed in individuals with lipodystrophy.

Hypertriglyceridemia and hyperglycemia should be managed by lifestyle change. Low fat diet, regular exercise, and aggressive glycemic controls are recommended. If hypertriglyceridemia persists despite changes in diet, regular exercise, and maintenance of euglycemia, individuals should be treated with fibrates and high doses of fish oils containing n-3 polyunsaturated fats. Aggressive glycemic control is pivotal for the prevention of the long-term complications of diabetes. Oral hypoglycemic drugs, particularly metformin, which may additionally reduce appetite, induce weight loss, and improve the polycystic ovary syndrome and hepatic steatosis, is a particularly attractive therapeutic choice. Insulin may also be used if hyperglycemia is not adequately controlled by oral hypoglycemia agents. Estrogens, whether taken for contraception, polycystic ovary syndrome, or postmenopausal symptoms, may exacerbate hypertriglyceridemia and should be avoided. Individuals with hypertriglyceridemia and hepatic steatosis should be advised to avoid drinking alcohol.



Rationale

Efficacy of metreleptin consists entirely of small observational studies. The largest was an NIDDK sponsored open-label single-arm study of individuals with generalized lipodystrophy (non-HIV-related) and diabetes, insulin resistance, or hypertriglyceridemia. There is some question about the size of the study, since the original publication reported 55 subjects (Chan, 2011), but a more recent abstract lists 64 and the prescribing information says 48. It is not clear why some individuals were excluded from the FDA-approved label.

Treatment with metreleptin reduced mean HbA1c from baseline at 4 months -1.2% (95% CI, -1.6 to -0.8) (n=40) and at 3 years -2.1% (95% CI, -3.2 to -1.1) (n=18). Among all individuals, the change in triglycerides from baseline to 4 months was -44.4 mg/dL (95% CI, -58.8 to -29.9) (n=40) and at 3 years it was -35.4 mg/dL (95% CI, -64.1 to -6.7) (n=19). These subjects were a heterogeneous group with varying type and level of metabolic abnormalities at baseline. In subgroups of individuals whose HbA1c and triglyceride levels were elevated at baseline, the HbA1c reduction at 4 months and 3 years were -1.4 (95% CI, -1.8 to -0.9) and -2.6 (95% CI, -3.8 to -1.3) (n=14). The mean reduction in triglycerides among individuals with elevated levels at baseline at 4 months and 3 years were -44.4 mg/dL (95% CI, -58.8 to -29.9) (n=30) and -51.2 mg/dL (95% CI, -87.5 to -14.8) (n=13), respectively. There was greater response in individuals with elevated HbA1c and triglycerides at baseline. These results were consistent with those from smaller studies.

Due to the subjects' heterogeneity and the absence of a control group, it is difficult to quantify the true treatment effect of metreleptin. Changes in concomitant medications, diet or exercise may have confounded the results. Eighty four percent of individuals displayed immunogenicity and expressed anti-metreleptin antibodies. Anti-metreleptin antibodies with neutralizing activity are associated with loss of endogenous leptin activity as well as loss of metreleptin efficacy, as occurred in 6% of study individuals.

Most common adverse reactions in clinical trials were headache (13%), hypoglycemia (13%), decreased weight (13%) and abdominal pain (10%). T-cell lymphoma has been reported in 2 individuals (4%). Both individuals had immunodeficiency and severely abnormal bone marrow biopsy specimens at baseline. However, there was one case of anaplastic large cell lymphoma in a individual receiving metreleptin who did not have hematological abnormalities before treatment. Eighty four percent of individuals displayed immunogenicity and expressed anti-metreleptin antibodies. Anti-metreleptin antibodies with neutralizing activity associated with adverse events consistent with loss of endogenous leptin activity and/or loss of metreleptin efficacy. Severe infection and/or worsening metabolic control have been reported as a result of anti-metreleptin antibodies (increases in HbA1c and/or triglycerides) and observed in 6% of



individuals. For these two specific reasons metreleptin is only available through the MYALEPT REMS program. There were cases of acute pancreatitis in 5 individuals (9%). All of these individuals had a history of pancreatitis and severe hypertriglyceridemia. Chronic renal adverse events reported in 5 individuals (9%), all of whom had a history of renal disease at baseline. Elevated LFT or events of liver disease are reported in 4 individuals (7%). Given the small number of individual exposures, it is difficult to assess the probability of other less common but serious adverse events occurring.

2015 Update

A literature search from January 1, 2014, to June 28, 2015, was conducted. No new studies were found that would affect this policy.

2016 Update

A literature search from July 1, 2015, to December 6, 2016, was conducted. No new studies were found that would affect this policy. Additional reference included.

2017 Update

A literature search from July 1, 2016 to November 1, 2017 was conducted. No new studies were found that would affect this policy.

2018 Update

A literature search from November 1, 2017, to October 31, 2018, was conducted. No new studies were found.

2019 Update

Reviewed Myalept (metreleptin) prescribing information and conducted a literature search from November 1, 2018, through November 30, 2019. No new information was identified that would require changes to this policy.



2020 Update

Reviewed Myalept (metreleptin) prescribing information and conducted a literature search from December 1, 2019, through September 30, 2020. No new information was identified that would require changes to this policy.

2021 Update

Reviewed Myalept (metreleptin) prescribing information and updated policy based on FDA-approved indication for Myalept and clinical studies referenced. Per prescribing information Myalept is indicated as an adjunct to diet and the individual is to follow a doctor-recommended diet for generalized lipodystrophy. Updated requirements for the metabolic abnormalities adding HbA_{1c} and triglyceride values based on the clinical studies. Added requirement drug is prescribed by or in consultation with an endocrinologist and added a daily dose limit of 10 mg/day which is the maximum dose listed in the prescribing information. For the re-authorization criteria added specific requirements that the individual is tolerating therapy and that there is a decrease in HbA_{1c} and/or fasting triglyceride levels from baseline.

2022 Update

Reviewed Myalept (metreleptin) prescribing information and conducted a literature search from October 1, 2020, through July 31, 2022. No new information was identified that would require changes to this policy.

2023 Update

Reviewed Myalept (metreleptin) prescribing information. No new information was identified that would require changes to this policy.



2024 Update

Reviewed Myalept (metreleptin) prescribing information. No new information was identified that would require changes to this policy.

2024 Update

Reviewed Myalept (metreleptin) prescribing information. Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information. Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12 months.

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History



Date	Comments
06/09/14	New policy, add to Prescription Drug section. Metreleptin (Myalept) may be considered medically necessary for treatment of congenital or acquired lipodystrophy when all criteria are met; all other uses are considered investigational. Approved by P&T Committee on May 22, 2014.
07/14/15	Annual Review. Policy updated with literature review. No change to policy statement.
01/01/17	Annual Review, approved December 13, 2016. Policy updated with literature review. No changes made to the policy statement. Additional reference included.
12/01/17	Annual Review, approved November 14, 2017. Updated Myalept criteria. One reference was added.
12/01/18	Annual Review, approved November 21, 2018. No new studies found.
01/01/20	Annual Review, approved December 10, 2019. No changes to policy statement.
12/01/20	Annual Review, approved November 3, 2020. No changes to policy statement.
08/01/21	Annual Review, approved July 13, 2021. Updated criteria removing requirement the diagnosis of leptin deficiency is by an endocrinologist. Added requirement drug is used as an adjunct to diet, updated requirements for the metabolic abnormalities, added requirement drug is prescribed by or in consultation with an endocrinologist, and added a daily dose limit. Updated the re-authorization criteria to document the individual is tolerating therapy and that there is a decrease in HbA _{1c} and/or fasting triglyceride levels from baseline.
10/01/22	Annual Review, approved September 12, 2022. No changes to policy statement.
06/01/23	Annual Review, approved May 22, 2023. No changes to policy statement.
08/01/24	Annual Review, approved July 8, 2024. No changes to policy statement.
05/01/25	Annual Review, approved April 21, 2025. Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information. Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12 months.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2025 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member



benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

