Clinical Policy: Metreleptin (Myalept)

Reference Number: CP.PHAR.425
Effective Date: 11.16.16
Last Review Date: 08.21
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Metreleptin (Myalept®) is a recombinant human leptin analog.

FDA Approved Indication(s)

Myalept is indicated as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy.

Limitation(s) of use:

- The safety and effectiveness of Myalept for the treatment of complications of partial lipodystrophy have not been established.
- The safety and effectiveness of Myalept for the treatment of liver disease, including nonalcoholic steatohepatitis (NASH), have not been established.
- Myalept is not indicated for use in patients with HIV-related lipodystrophy.
- Myalept is not indicated for use in patients with metabolic disease, without concurrent evidence of generalized lipodystrophy.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Myalept is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Leptin Deficiency (must meet all)**:**

1. Diagnosis of leptin deficiency;
2. Age ≥ 1 year;
3. Member has congenital or acquired generalized lipodystrophy;
4. Dose does not exceed (a or b):
   a. Body weight ≤ 40 kg: 0.13 mg/kg per day;
   b. Body weight > 40 kg: 10 mg per day.

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Leptin Deficiency (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed (a or b):
   a. Body weight ≤ 40 kg: 0.13 mg/kg per day;
   b. Body weight > 40 kg: 10 mg per day.

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents;
B. General obesity not associated with congenital leptin deficiency;
C. HIV-related lipodystrophy;
D. Liver disease, including NASH.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
HIV: human immunodeficiency virus
NASH: nonalcoholic steatohepatitis

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - General obesity not associated with congenital leptin deficiency: Myalept has not been shown to be effective in treating general obesity, and the development of anti-metreleptin antibodies with neutralizing activity has been reported in obese patients treated with Myalept
  - Hypersensitivity to metreleptin
- Boxed warning(s): risk of anti-metreleptin antibodies with neutralizing activity and risk of lymphoma
  - Because of these risks, Myalept is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Myalept REMS Program

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy	Weight ≤ 40 kg: 0.06 to 0.13 mg/kg SC QD (adjust in increments of 0.02 mg/kg) Weight > 40 kg: Males: 2.5 to 10 mg SC QD (adjust in increments of 1.25 to 2.5 mg/day) Females: 5 to 10 mg SC QD (adjust in increments of 1.25 to 2.5 mg/day)	Weight ≤ 40 kg: 0.13 mg/kg/day Weight > 40 kg: 10 mg/day

VI. Product Availability

Lyophilized cake in vial to be reconstituted: 11.3 mg/vial (5 mg/mL after reconstitution)

VII. References

1. Myalept Prescribing Information. Cambridge, MA: Aegerion Pharmaceuticals, Inc; September 2020. Available at http://www.myaleptpro.com. Accessed on March 18, 2021.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590, C9399	MYALEPT 11.3MG Solution Reconstituted

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Minor changes to verbiage and grammar. References updated.	1.17.17	11.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2018 annual review: policies combined for Centene HIM (new) and Commercial lines of business; no significant changes; age added; approval durations for Commercial modified from length of benefit to 6/6 months; added HIV-related lipodystrophy and liver disease as indications not covered per PI; references reviewed and updated.	04.02.18	08.18
3Q 2019 annual review: no significant changes; added Medicaid line of business to CP.PCH.05 and retired CP.PCH.05; references reviewed and updated.	04.22.19	08.19
3Q 2020 annual review: no significant changes; references reviewed and updated.	04.20.20	08.20
3Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	03.18.21	08.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.