PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Myalept (metreleptin)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Myalept was approved in 2014 to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy. The defining feature of lipodystrophy is the selective loss of subcutaneous adipose tissue. Leptin is a hormone secreted by adipose tissue that informs the brain of the status of energy stores in the body. The leptin deficiency resulting from adipose tissue loss contributes to metabolic abnormalities. The replacement of leptin with metreleptin, which mimics native leptin, helps improve metabolic parameters. It must be used as an adjunct to diet, the fundamental treatment for lipodystrophy. It is only available through the Myalept REMS program.

Myalept (metreleptin) will be considered for coverage when the following criteria are met:

Lipodystrophy

For **initial** authorization:

1. Medication must be prescribed by or in consultation with an endocrinologist; AND
2. Member has a diagnosis of congenital or acquired generalized lipodystrophy (CGL or AGL); AND
3. Member has a metabolic abnormality (e.g. diabetes, hypertriglyceridemia, insulin resistance) that has not responded to optimized standard therapy (e.g. metformin, insulin, statins, fibrates); AND
4. Member has failed dietary/lifestyle modifications and medication is prescribed in conjunction with ongoing diet management; AND
5. Member does not have any of the following:
   a) HIV-associated lipodystrophy;
   b) General obesity (without leptin deficiency).
6. **Dosage allowed/Quantity limit:** Administer as a subcutaneous injection once daily. See package insert for adult and pediatric dosing charts. The maximum dose is 10mg/day (2mL). Quantity Limit: 30 vials per 30 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must demonstrate improved signs and symptoms of leptin deficiency, such as reductions in HbA1c, fasting glucose, or triglycerides.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Myalept (metreleptin) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
01/08/2021	New policy for Myalept created.
09/25/2023	Updated references; added quantity limit; added dosing information; removed initial criteria requirement from reauthorization.

References:

1. Myalept (metreleptin) [package insert]. Dublin, Ireland: Amryt Pharmaceuticals DAC; 2022.
2. Brown RJ, Araujo-Vilar D, Cheung PT, et al. The Diagnosis and Management of Lipodystrophy Syndromes: A Multi-Society Practice Guideline. *J Clin Endocrinol Metab*. 2016;101(12):4500-4511. doi:10.1210/jc.2016-2466
3. Handelsman Y, Oral EA, Bloomgarden ZT, et al. The clinical approach to the detection of lipodystrophy - an AACE consensus statement. *Endocr Pract*. 2013;19(1):107-116. doi:10.4158/endp.19.1.v767575m65p5mr06
4. Meehan CA, Cochran E, Kassai A, Brown RJ, Gorden P. Metreleptin for injection to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy. *Expert Rev Clin Pharmacol*. 2016;9(1):59-68. doi:10.1586/17512433.2016.1096772
5. Araújo-Vilar D, Santini F. Diagnosis and treatment of lipodystrophy: a step-by-step approach. *J Endocrinol Invest*. 2019;42(1):61-73. doi:10.1007/s40618-018-0887-z

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