Clinical Policy Title:	metreleptin
Policy Number:	RxA.230
Drug(s) Applied:	Myalept®
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

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

1. Diagnosis of leptin deficiency;
2. Age ≥ 1 year;
3. Prescribed by or in consultation with an endocrinologist;
4. Member has congenital or acquired generalized lipodystrophy;
5. 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
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
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
Commercial: 6 months
Medicaid: 12 months

References

1. National Organization for Rare Disorders. Congenital generalized lipodystrophy. Available at: https://rarediseases.org/rare-diseases/congenital-generalized-lipodystrophy/. Accessed December 27, 2022.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020

Policy was reviewed: 1. Policy description table was updated. 2. Limitation(s) of use was updated. 3. Initial therapy and continued therapy approval duration for “commercial” was updated. 4. References were updated.	06/19/2020	09/14/2020
Policy was reviewed: 1. Last review date was updated. 2. Continued Therapy criteria II.A.1 was rephrased from "Currently receiving medication that has been authorized by RxAdvance...". 3. Trademark symbol updated to “®” from “™” for drug name Myalept®. 4. References were reviewed and updated.	02/19/2021	06/10/2021
Policy was reviewed: 1. Initial Approval Criteria I.A.3: Updated to add prescriber criteria. 2. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3. References were reviewed and updated.	01/20/2022	04/18/2022
Policy was reviewed: 1. References were reviewed and updated.	12/27/2022	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023