

Clinical Policy Title:	metreleptin
Policy Number:	RxA.230
Drug(s) Applied:	Myalept®
Original Policy Date:	02/07/2020
Last Review Date:	12/11/2025
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. Member has congenital or acquired generalized lipodystrophy.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Leptin Deficiency (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. National Organization for Rare Disorders. Congenital generalized lipodystrophy. Available at: <https://rarediseases.org/rare-diseases/congenital-generalized-lipodystrophy/>. Accessed August 28, 2024.

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	02/19/2021	06/10/2021

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>II.A.1 was rephrased from "Currently receiving medication that has been authorized by RxAdvance...".</p> <p>3. Trademark symbol updated to “®” from “™” for drug name Myalept®.</p> <p>4. References were reviewed and updated.</p>		
<p>Policy was reviewed:</p> <p>1. Initial Approval Criteria I.A.3: Updated to add prescriber criteria.</p> <p>2. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".</p> <p>3. References were reviewed and updated.</p>	01/20/2022	04/18/2022
<p>Policy was reviewed:</p> <p>1. References were reviewed and updated.</p>	12/27/2022	04/13/2023
<p>Policy was reviewed.</p>	10/19/2023	10/19/2023
<p>Policy was reviewed:</p> <p>1. Removed age restrictions.</p> <p>2. Removed prescriber restrictions.</p> <p>3. Removed dose restrictions.</p> <p>4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days.</p> <p>5. Removed reauthorization requirement for positive response to therapy.</p> <p>6. Updated approval duration verbiage.</p> <p>7. References were reviewed and updated.</p>	08/28/2024	09/13/2024
<p>Policy was reviewed.</p>	12/05/2024	N/A
<p>Policy reviewed.</p>	12/11/2025	12/11/2025