

Myalept Prior Authorization Program Summary

POLICY REVIEW CYCLE

Effective Date
12-15-2025

Date of Origin

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Myalept	Metreleptin For Subcutaneous Inj 11.3 MG	11.3 MG	M ; N ; O ; Y	N		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Myalept	Metreleptin For Subcutaneous Inj 11.3 MG	11.3 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Initial Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has ALL of the the following: <ol style="list-style-type: none"> 1. A diagnosis of congenital generalized lipodystrophy (CGL) or acquired generalized lipodystrophy (AGL) AND 2. A leptin deficiency confirmed by laboratory testing (i.e., less than 12 ng/mL) prior to initiating the requested agent AND

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	<p>3. At least ONE of the following complications related to lipodystrophy:</p> <ul style="list-style-type: none"> A. Diabetes mellitus OR B. Hyperinsulinemia (i.e., greater than or equal to 30 microU/mL) OR C. Hypertriglyceridemia (i.e., greater than or equal to 200 mg/dL) AND <p>4. Has had baseline HbA1c, triglycerides, and fasting insulin levels measured prior to initiating the requested agent AND</p> <p>5. Tried and had an inadequate response to the maximum tolerable dose of a conventional agent for complications related to lipodystrophy OR</p> <p>B. The patient has another FDA labeled indication for the requested agent and route of administration AND</p> <p>2. BOTH of the following:</p> <ul style="list-style-type: none"> A. The patient has had an inadequate response to lifestyle modification (i.e., diet modification and exercise) AND B. The patient will continue lifestyle modifications with the requested agent AND <p>3. The patient does NOT have any of the following limitations of use for the requested agent:</p> <ul style="list-style-type: none"> A. Partial lipodystrophy B. Liver disease (including non-alcoholic steatohepatitis [NASH] or metabolic associated steatohepatitis [MASH]) C. HIV-related lipodystrophy D. Metabolic disease (e.g., diabetes mellitus, hypertriglyceridemia) without evidence of generalized lipodystrophy AND <p>4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</p> <p>5. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>6. ONE of the following:</p> <ul style="list-style-type: none"> A. The requested quantity (dose) is within FDA labeled dosing for the requested indication OR B. There is information in support of therapy with a higher dose for the requested indication <p>Length of Approval:</p> <p>BCBSOK: 36 months ALL other plans: 12 months</p> <p>The requested agent will also be approved when ONE of the following is met:</p> <ul style="list-style-type: none"> 1. The request is for a BCBS MT Fully Insured or MT HIM member AND <ul style="list-style-type: none"> A. The patient is under the age of 18 years old AND B. The patient does NOT have any FDA labeled contraindications to the requested agent AND C. The patient has an indication that is supported in TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] AND D. There is support for an age in the patient's given age bracket in TWO articles from major peer-reviewed professional medical journals as generally safe and effective. The age brackets are: 1. infancy (birth up to, but not including, 2 years of age), 2. childhood (2 years of age through 11 years of age), 3. adolescence (12 years of age through 17 years of age). Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled

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	<p>clinical trials. NOTE: Case studies are not acceptable [journal articles required]</p> <p>OR</p> <ol style="list-style-type: none"> 2. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following: <ol style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. The requested indication is a rare disease AND C. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. ALL of the following: <ol style="list-style-type: none"> A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND C. The patient does NOT have any FDA labeled contraindications to the requested agent AND D. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months ALL other plans: 12 months</p> <p>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] AND 2. The patient has had clinical benefit with the requested agent AND 3. The patient will continue lifestyle modifications (i.e., diet and exercise) with the requested agent AND 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 5. The patient does NOT have any FDA labeled contraindications to the requested agent AND 6. ONE of the following:

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	<p data-bbox="354 180 1354 237">A. The requested quantity (dose) is within FDA labeled dosing for the requested indication OR</p> <p data-bbox="354 239 1377 296">B. There is information in support of therapy with a higher dose for the requested indication</p> <p data-bbox="232 331 500 363">Length of Approval:</p> <p data-bbox="232 401 483 428">BCBSOK: 36 months</p> <p data-bbox="232 430 570 457">ALL other plans: 12 months</p>