



# Imcivree Prior Authorization with Quantity Limit Program Summary

## POLICY REVIEW CYCLE

**Effective Date**

11-01-2025

**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
Imcivree	setmelanotide acetate subcutaneous soln	10 MG/ML	M ; N ; O ; Y	N		

## POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Imcivree	setmelanotide acetate subcutaneous soln	10 MG/ML	10	Vials	30	DAYS			

## CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Imcivree	setmelanotide acetate subcutaneous soln	10 MG/ML	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

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			2026 ; Topaz ; Whole Foods

## CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Imcivree	setmelanotide acetate subcutaneous soln	10 MG/ML	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><b>Initial Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>1. ONE of the following: <ol style="list-style-type: none"> <li>A. ALL of the following: <ol style="list-style-type: none"> <li>1. The patient has a diagnosis of monogenic obesity due to pro-opiomelanocortin (POMC) deficiency, proprotein convertase subtilisin/kexin type 1 (PCSK1) deficiency, or leptin receptor (LEPR) deficiency <b>AND</b></li> <li>2. Genetic testing with an FDA-approved test has confirmed variants in POMC, PCSK1, or LEPR genes (medical records required) <b>AND</b></li> <li>3. The patient's genetic status is bi-allelic, homozygous, or compound heterozygous (NOT double heterozygous) <b>AND</b></li> <li>4. The patient's genetic variant is interpreted as pathogenic, likely pathogenic, OR of uncertain significance (VUS) <b>AND</b></li> <li>5. The patient's genetic variant is NOT classified as benign or likely benign <b>OR</b></li> </ol> </li> <li>B. BOTH of the following: <ol style="list-style-type: none"> <li>1. The patient has a diagnosis of syndromic obesity due to Bardet-Biedl syndrome (BBS) <b>AND</b></li> <li>2. The patient's diagnosis has been clinically confirmed by four primary features OR three primary and two secondary features (medical records required) (i.e., primary features [rod-cone dystrophy, polydactyly, obesity, genital anomalies, renal anomalies, learning difficulties]; secondary features [speech delay, developmental delay, diabetes mellitus, dental anomalies, congenital heart disease,</li> </ol> </li> </ol> </li> </ol>

Module	Clinical Criteria for Approval
	<p style="text-align: center;">bracydactyly/syndactyly, ataxia/poor coordination, anosmia/hyposmia]) <b>AND</b></p> <ol style="list-style-type: none"> <li>2. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> <li>A. The patient's age is within FDA labeling for the requested indication for the requested agent <b>OR</b></li> <li>B. There is support for using the requested agent for the patient's age for the requested indication <b>AND</b></li> </ol> </li> <li>3. ONE of the following: <ol style="list-style-type: none"> <li>A. For adult patients, the body mass index (BMI) is greater than or equal to 30 kg/m<sup>2</sup> <b>OR</b></li> <li>B. For pediatric patients, weight is greater than or equal to 95th percentile (for POMC, PCSK1, or LEPR) or 97th percentile (for BBS) using growth chart assessments <b>AND</b></li> </ol> </li> <li>4. ONE of the following: <ol style="list-style-type: none"> <li>A. The patient is newly starting therapy <b>OR</b></li> <li>B. ONE of the following: <ol style="list-style-type: none"> <li>1. For patients with obesity due to POMC, PCSK1, or LEPR deficiency, ONE of the following: <ol style="list-style-type: none"> <li>A. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy <b>OR</b></li> <li>B. The patient has received at least 16 weeks of therapy, and has achieved a weight loss of ONE of the following: <ol style="list-style-type: none"> <li>1. Weight loss of greater than or equal to 5% of baseline body weight (prior to the initiation of the requested agent) <b>OR</b></li> <li>2. For patients with continued growth potential, weight loss of greater than or equal to 5% of baseline BMI (prior to the initiation of the requested agent) <b>OR</b></li> </ol> </li> </ol> </li> <li>2. For patients with obesity due to BBS, ONE of the following: <ol style="list-style-type: none"> <li>A. The patient is currently being treated and has received less than one year of therapy <b>OR</b></li> <li>B. The patient has received at least one year of therapy, and has achieved a weight loss of ONE of the following: <ol style="list-style-type: none"> <li>1. Weight loss of greater than or equal to 5% of baseline body weight (prior to the initiation of the requested agent) <b>OR</b></li> <li>2. For patients aged less than 18 years, weight loss of greater than or equal to 5% of baseline BMI (prior to the initiation of the requested agent) <b>AND</b></li> </ol> </li> </ol> </li> </ol> </li> <li>5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist, metabolic disorders), or the prescriber has consulted with a specialist in the area of the patient's diagnosis <b>AND</b></li> <li>6. The patient does NOT have any FDA labeled contraindications to the requested agent</li> </ol> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months</p> <p>BCBSIL and BCBSMT: 12 months</p> <p>ALL other plans: 4 months for POMC, PCSK1, or LEPR deficiency; 12 months for BBS</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p><b>The requested agent will also be approved when ONE of the following is met:</b></p> <ol style="list-style-type: none"> <li>1. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following:</li> </ol> </li></ol>

Module	Clinical Criteria for Approval
	<p>A. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></p> <p>B. The requested indication is a rare disease <b>AND</b></p> <p>C. ONE of the following:</p> <ol style="list-style-type: none"> <li>1. The patient has another FDA labeled indication for the requested agent and route of administration <b>OR</b></li> <li>2. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>OR</b></li> </ol> <p>2. ALL of the following:</p> <ol style="list-style-type: none"> <li>A. The member resides in Ohio <b>AND</b></li> <li>B. The plan is Fully Insured or HIM Shop (SG) <b>AND</b></li> <li>C. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></li> <li>D. ONE of the following: <ol style="list-style-type: none"> <li>1. The patient has another FDA labeled indication for the requested agent and route of administration <b>OR</b></li> <li>2. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>OR</b></li> <li>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]</li> </ol> </li> </ol> <p><b>Non-oncology compendia allowed:</b> DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p><b>Oncology compendia allowed:</b> 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><b>Length of Approval:</b></p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p><b>Renewal Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>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] <b>AND</b></li> <li>2. ONE of the following: <ol style="list-style-type: none"> <li>A. For adult patients, the patient has achieved and maintained weight loss of greater than or equal to 5% of baseline body weight (prior to the initiation of the requested agent) <b>OR</b></li> <li>B. ONE of the following: <ol style="list-style-type: none"> <li>1. For patients with POMC, PCSK1, or LEPR deficiency AND continued growth potential, the patient has achieved and maintained weight loss of greater than or equal to 5% of baseline BMI (prior to the initiation of the requested agent) <b>OR</b></li> </ol> </li> </ol> </li> </ol>

Module	Clinical Criteria for Approval
	<p>2. For patients with BBS AND are aged less than 18 years, the patient has achieved and maintained weight loss of greater than or equal to 5% of baseline BMI (prior to the initiation of the requested agent) <b>AND</b></p> <p>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist, metabolic disorders) or the prescriber has consulted with a specialist in the area of the patient's diagnosis <b>AND</b></p> <p>4. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

### QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p><b>Quantity Limit for the Target Agent(s)</b> will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the program quantity limit <b>OR</b></li> <li>2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> <li>A. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. There is support for therapy with a higher dose for the requested indication <b>OR</b></li> </ol> </li> <li>B. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit</li> </ol> </li> </ol> </li> </ol> <p><b>Length of Approval:</b></p> <p>BCBSIL: 12 months</p> <p>ALL other plans:</p> <p>Initial - 4 months for POMC, PCSK1, or LEPR deficiency; 12 months for BBS</p> <p>Renewal - 12 months</p>