

BC PharmaCare Drug Information

The drug below is being considered for coverage under the BC PharmaCare program. PharmaCare is a government-funded drug plan that helps B.C. residents with the cost of eligible prescription drugs and medical supplies. For more information about PharmaCare, visit the [PharmaCare website](#).

PharmaCare reviews each drug for treating a specific illness or medical condition (also called an “indication”). If PharmaCare decides to cover a drug, that coverage applies only to the indication(s) specified. In some cases, PharmaCare covers a drug only for people who have not responded to other drugs that treat the same indication.

More information about the PharmaCare drug review process is provided on the last page of this document.

Drug information	
Generic name (scientific name)	setmelanotide
Brand name	Imcivree®
Manufacturer	Rhythm Pharmaceuticals
Indication	Weight management in adult and pediatric patients 4 years of age and older with acquired hypothalamic obesity.
Has the drug been reviewed by CDA-AMC, or will CDA-AMC be reviewing it? (See note below.)	Yes For more information about the CDA-AMC Reimbursement Review (CRR) of setmelanotide (Imcivree®), Search the CDA-AMC Reports .
Public input start date	Wednesday, July 29, 2026
Public input closing date	Tuesday, August 25, 2026, at 11:59 pm
How is the drug taken?	Setmelanotide is given by subcutaneous (under the skin) injection.
How often is the drug taken?	Setmelanotide is injected once daily.

General drug and/or drug study information

Hypothalamic obesity (HO) is a form of obesity caused by damage to the hypothalamus, the part of the brain that regulates energy balance and automatic body functions such as heart rate, breathing rate, blood pressure, digestion, and sweating. Acquired HO (aHO) can occur when tumours affect the hypothalamus, or as a result of tumor treatments, such as surgery or radiation. It can also occur after a traumatic brain injury or from inflammatory causes.

aHO is usually managed with weight-management approaches, including lifestyle interventions such as diet management and physical activity, followed by off-label anti-obesity medications. There are currently no Health Canada-approved treatments for weight management in aHO patients.

Setmelanotide belongs to a class of medicines called melanocortin 4 (MC4) receptor agonists. It works on pathways in the brain to help reduce appetite and increase the amount of energy the body uses.

Studies looked at the following:

- Change in body mass index (BMI)^a and BMI z-score^b, and BMI response and BMI z-score response
- Weight outcomes as measured by the average percent change in body weight
- Hunger outcomes as measured by the average change in the weekly average of daily most hunger scores
- Weekly average of excessive hunger and difficulty feeling full (hyperphagia) outcomes as measured by Symptoms of Hyperphagia composite score
- Fatigue outcomes as measured by the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue) score
- Health-Related Quality of Life (HRQoL) as measured by the Impact of Weight on Quality of Life-Lite (IWQoL-Lite), and Impact of Weight on Quality of Life-Kids (IWQoL-Kids) measuring tools
- Bad reactions
- Serious bad reactions
- Patients leaving the trial due to bad reactions
- Bad reactions of special interest including dark spots on the skin (hyperpigmentation), non-cancerous (benign), cancerous (malignant), and unspecified tumours, psychiatric disorders,

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	reproductive events (increased erections, spontaneous penile erections, and genital pain)
Other considerations	None

Note:

CDA-AMC ([Canada's Drug Agency-L'Agence des Médicaments du Canada](#)) is a national organization that reviews drugs on behalf of Canadian public sector plans when drug manufacturers want those plans to provide coverage for the drug. For detailed information about the PharmaCare drug review process, including the role of the CDA-AMC Reimbursement Review (CRR) in that process, visit [How PharmaCare Decides Which Drugs to Cover](#).

Table of Comparators Used to Treat the Same Indication		
Generic Name (Brand Name) of Drug Comparator	Dosage Form	PharmaCare Status (if and how the drug is already covered)
setmelanotide (Imcivree®)	Multiple-dose vial 10 mg/mL	Under Review

^a BMI is a person's weight in kilograms (or pounds) divided by the square of height in meters (or feet).

^b A z-score is a tool that shows how a patient's measurements (height, weight, BMI) compared to other people of the same age and sex. A positive z-score means the measurement is higher than the average, while a negative z-score means it is lower than average.

The Drug Review Process in B.C.

A manufacturer submits a request to the Ministry of Health (Ministry).

An independent national organization called [Canada's Drug Agency \(CDA-AMC\)](#) provides evidence-based recommendations to public drug plans across Canada through its reimbursement review process.

As part of the CDA-AMC's Clinical Reimbursement Review process, the Canadian Drug Expert Committee (CDEC) makes reimbursement recommendations for non-oncology pharmaceuticals to the participating federal, provincial, and territorial publicly funded drug plans. In developing its recommendations, the CDEC considers:

- whether the drug is safe and effective
- what the drug costs and whether it is a good value to the citizens of B.C.
- ethical considerations related to covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes a BC PharmaCare coverage decision by considering:

- existing BC PharmaCare policies, programs and resources
- the evidence-informed advice of the CDA-AMC
- the recommendations and reimbursement conditions of the CDEC
- if a Ministry Initiated review, the advice of an independent expert group called the Drug Benefit Council (DBC)
- BC-specific patient input collected through the Your Voice website
- drugs already covered by BC PharmaCare that treat similar medical conditions
- the overall cost of covering the drug

Visit [BC PharmaCare](#) and [Drug reviews](#) for more information.

This document provides information only.

It does not take the place of advice from a physician or other qualified health care provider.