



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 March 2026
EMADOC-1700519818-3024392
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Imcivree setmelanotide

On 26 March 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Imcivree. The marketing authorisation holder for this medicinal product is Rhythm Pharmaceuticals Netherlands B.V.

The CHMP adopted a new indication as follows:

Imcivree is indicated for the treatment of obesity and the control of hunger in adults and children 4 years of age and above with acquired hypothalamic obesity (aHO) due to hypothalamic injury or impairment.

For information, the full indications for Imcivree will now be:²

IMCIVREE is indicated for the treatment of obesity and the control of hunger in adults and children 4 years of age and above with acquired hypothalamic obesity (aHO) due to hypothalamic injury or impairment.

IMCIVREE is indicated for the treatment of obesity and the control of hunger associated with genetically confirmed Bardet Biedl syndrome (BBS) in adults and children 2 years of age and above.

IMCIVREE is indicated for the treatment of obesity and the control of hunger associated with genetically confirmed loss-of-function biallelic pro-opiomelanocortin (POMC), including PCSK1, deficiency or biallelic leptin receptor (LEPR) deficiency in adults and children 2 years of age and above.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union

¹ Summary of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

² New text in bold



languages after a decision on this change to the marketing authorisation has been granted by the European Commission.