

New Drug Manufacturer Report

Section	Data element	Field type	Imcivree
1. Drug identification	National drug code (11-digit NDC)	Numeric	72829-0010-01
	Drug name	Text	Imcivree
2. Drug Launch Information	Description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally	Text	<p>Marketing: Imcivree is the first and only FDA approved treatment for chronic weight management in adult and pediatric patients 6 years of age and older with obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency. Rhythm's approach will focus on educating health care providers on how to diagnose and treat patients efficiently to relieve symptoms for patients. Educational materials will be provided across the patient journey, to both HCPs and to families, and highlight access and affordability support for Imcivree to ensure rapid access to life saving therapy</p> <p>Pricing: Imcivree (Setmelanotide injection) has been developed for the treatment of obesity due to POMC, PCSK1 or LEPR deficiency are ultra-rare diseases caused by variants in POMC, PCSK1 or LEPR genes that impair the melanocortin-4 (MC4) receptor pathway. Imcivree provides an option where there is none currently and delivers a safe, effective treatment that reduces the symptoms in patients. Imcivree is priced responsibly compared to similar orphan agents with significant clinical benefit and disease modification. Pricing accounts for development costs, complexity of manufacturing, distribution, and storage. Rhythm demonstrates a strong commitment to patients and their ability to get access to care with support programs that leaves no patient behind.</p>
	Estimated volume of patients who may be prescribed the drug	Numeric	200
	Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	Text	Y
	Date and price of acquisition if the drug was not developed by the manufacturer	Text	NA