Imcivree (Setmelanotide)

EXCEPTION DRUG STATUS (EDS) REQUEST FORM

Fax: (204) 942-2030 or 1-877-208-3588

Prescriber Name:	**Fax Number:**
Prescriber Address:	**Phone Number:**
	Prescriber License Number (NOT Billing Number):

Patient First Name:	**PHIN:**	**MHSC:**
Patient Last Name:	**Patient's Date of Birth:**	
◯ **Initial Request**	◯ **Renewal Request**	
Strength, Dosage Form and Regimen:	**Expected Duration of Therapy**	

Exception Drug Status (EDS) approval is only granted upon demonstration that the patient meets the coverage criteria of the EDS listing. Please provide the following details about how this patient meets the specific criteria for coverage. Manitoba Health may request additional documentation to support this EDS request.

For INITIAL Request:

Diagnosis/Indication:	◯ Weight management for patients with obesity associated with Bardet-Biedl syndrome (BBS).
	◯ Other: _____

Please select YES or NO to the following:

Patient is 6 years of age or older.	◯ YES	◯ NO
Patient has obesity associated with clinically or genetically confirmed Bardet-Biedl syndrome (BBS).	◯ YES	◯ NO

☐ **If Clinically Confirmed:**

Please specify the primary and/or secondary features of BBS the patient is diagnosed with based on the Beales criteria:

- Primary features: _____
- Secondary features: _____

☐ **If Genetically Confirmed:**

- Please provide a copy of the patient's genetic testing result.

Patient is under the care of an endocrinologist, pediatric endocrinologist and/or specialist in weight management or obesity.	◯ YES	◯ NO

Please provide the following baseline information (i.e., prior to treatment initiation with setmelanotide):

Patient's baseline total body weight: _____ **Date:** _____

Patient's baseline BMI (or BMI Z score): _____ **Date:** _____

For INITIAL Renewal:

Patient remains under the care of an endocrinologist, pediatric endocrinologist and/or specialist in weight management or obesity.	◯ YES	◯ NO

For patients 12 years of age and older: • Patient has had a 5% or greater reduction in body mass index (BMI) or total body weight. OR **For patients 6 to 11 years of age:** • Patient has had a reduction of 0.20 or greater in BMI Z score. **Patient's total body weight: _____ Date: _____** **Patient's BMI (or BMI Z score): _____ Date: _____**	◯ YES	◯ NO
Additional Relevant Clinical Information:		

For ONGOING Renewals:		
Patient remains under the care of an endocrinologist, pediatric endocrinologist and/or specialist in weight management or obesity.	◯ YES	◯ NO
Patient has maintained the response to setmelanotide achieved at the initial renewal. **Patient's total body weight: _____ Date: _____** **Patient's BMI (or BMI Z score): _____ Date: _____**	◯ YES	◯ NO
Additional Relevant Clinical Information:		

Prescriber Signature and Date:	
☐ **I have discussed with the patient that the purpose of releasing their information to Manitoba Health, Seniors and Long-Term Care is to obtain Exception Drug Status for prescription coverage.**	
Date:	Prescriber Signature: