SENTARA HEALTH PLANS

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-800-750-9692.** No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization may be delayed.**

Drug Requested: Imcivree® (setmelanotide)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy:** _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

Quantity Limit: 9 vials per month (1 mL = 1 vial)

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ **Diagnosis: pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency**

Initial Authorization: 6 months

- ❑ Prescribed by or in consultation with an endocrinologist, a geneticist, or an expert in rare genetic disorders of obesity
- ❑ Member must have homozygous or compound heterozygous variants in POMC, PCSK1, or LEPR
- ❑ Member must be 2 years of age or older
- ❑ Member must meet **ONE** of the following age-appropriate obesity requirements:
  - ❑ ≥30 kg/m^2 (age ≥18 years)
  - ❑ ≥95th percentile for age on growth chart assessment (age <18 years)

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Reauthorization: 12 months. All criteria that apply must be checked for approval. To support each line checked, all documentation (lab results, diagnostics, and/or chart notes) must be provided or request may be denied.

- ❑ Member has sustained weight loss achieved during initial treatment period as defined by **ONE** of the following:
  - ❑ ≥ 5% reduction of baseline body weight (or ≥ 5 kg if <100 kg) after the initial 6-month approval
  - ❑ ≥ 10% reduction of baseline body weight has been achieved and maintained for any subsequent approval after the initial 6-month period

❑ Diagnosis: monogenic or syndromic obesity due to Bardet-Biedl syndrome (BBS)

Initial Authorization: 6 months

- ❑ Prescribed by or in consultation with an endocrinologist, a geneticist, or an expert in rare genetic disorders of obesity
- ❑ Member has a diagnosis of monogenic or syndromic obesity due to Bardet-Biedl syndrome (BBS) **(must submit clinical documentation confirming diagnosis by genetic testing or per Beales, 1999 with either 4 primary features or 3 primary and 2 secondary features)**
- ❑ Member must be 2 years of age or older
- ❑ Member must have participated in a weight loss treatment plan (i.e., nutritional counseling, an exercise regimen and/or a calorie/fat-restricted diet) in the past 6 months
- ❑ Member must meet **ONE** of the following age-appropriate obesity requirements:
  - ❑ BMI ≥30 kg/m^2 (age ≥18 years)
  - ❑ BMI > 97th percentile for age using growth chart assessments (age <18 years)

Reauthorization: 12 months. All criteria that apply must be checked for approval. To support each line checked, all documentation (lab results, diagnostics, and/or chart notes) must be provided or request may be denied.

- ❑ Member has lost at least 5% of baseline body weight or 5% of baseline BMI for members age < 18 years during the initial treatment period, and/or has sustained weight loss of at least 5% of baseline body weight or BMI for members age < 18 years since last approval of the medication

❑ Diagnosis: Acquired hypothalamic obesity

Initial Authorization: 6 months

- ❑ Prescribed by or in consultation with an endocrinologist or other physician who specializes in metabolic disorders
- ❑ Member has a diagnosis of acquired hypothalamic obesity following hypothalamic tumor, hypothalamic lesion, or hypothalamic damage or injury **(must submit MRI and chart note documentation confirming diagnosis and medical history)**

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- ❑ Member must be 4 years of age or older
- ❑ Member must have participated in a weight loss treatment plan (i.e., nutritional counseling, an exercise regimen and/or a calorie/fat-restricted diet) in the past 6 months including use of pharmacotherapy (i.e. stimulant/weight loss medication, GLP-1 agonist medication) or has had trial of other weight loss intervention (i.e. Roux-en-Y gastric bypass, behavioral therapy; etc.) **(must submit documentation of treatment plan)**
- ❑ Member must meet **ONE** of the following age-appropriate obesity requirements:
  - ❑ BMI ≥30 kg/m^2 (age ≥18 years)
  - ❑ BMI ≥ 95th percentile for age using growth chart assessments (age <18 years)
- ❑ Member has **NOT** had bariatric surgery within the last 2 years
- ❑ Member does **NOT** have a diagnosis of Prader-Willi syndrome (PWS)

Reauthorization: 12 months. All criteria that apply must be checked for approval. To support each line checked, all documentation (lab results, diagnostics, and/or chart notes) must be provided or request may be denied.

- ❑ Member has lost at least 5% of baseline body weight or at least 5% of baseline BMI for members age < 18 years during the initial treatment period, and/or has sustained weight loss of at least 5% of baseline body weight if >18 years of age or at least 5% of baseline BMI for members age < 18 years since last approval of the medication

Medication being provided by a Specialty Pharmacy – Proprium Rx

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.
Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*