NC Medicaid
Outpatient Pharmacy Prior Approval Criteria
Imcivree

Effective Date: xx/xx/xxxx

DRAFT

Therapeutic Class Code: J8F
Therapeutic Class Description: Anti-Obesity – Melanocortin 4 Receptor Agonists

Medication
Imcivree (setmelanotide acetate)

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of

Age 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.

2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide,* and on the EPSDT provider page. The Web addresses are specified below.

   NCTracks Provider Claims and Billing Assistance Guide: https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

   EPSDT provider page: https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Clinical Coverage

- **ONE** of the following:
  - **ALL** of the following:
    - The beneficiary has a diagnosis of monogenic obesity due to proopiomelanocortin (POMC) deficiency, proprotein convertase subtilisin/kexin type 1 (PCSK1) deficiency, or leptin receptor (LEPR) deficiency **AND**
    - Genetic testing with an FDA-approved test has confirmed variants in POMC, PCSK1, or LEPR genes (medical records required) **AND**
    - The beneficiary 's genetic status is bi-allelic, homozygous, or compound heterozygous (NOT double heterozygous) **AND**
    - The beneficiary's genetic variant is interpreted as pathogenic, likely pathogenic, OR of uncertain significance (VUS) **AND**
    - The beneficiary's genetic variant is NOT classified as benign or likely benign **OR**
  - **BOTH** of the following**:**
    - The beneficiary has a diagnosis of syndromic obesity due to Bardet-Biedl syndrome (BBS) **AND**
    - The beneficiary 's diagnosis has been clinically confirmed by four primary features OR three primary and two secondary features (medical records required) (i.e., primary features [rod-cone dystrophy, polydactyly, obesity, genital anomalies, renal anomalies, learning difficulties]; secondary features [speech delay, developmental delay, diabetes mellitus, dental anomalies, congenital heart disease, bracydactyly/syndactyly, ataxia/poor coordination, anosmia/hyposmia]) **AND**
- The beneficiary is age 2 and older **AND**
- **ONE** of the following:
  - For adult beneficiaries, the body mass index (BMI) is greater than or equal to 30 kg/m^2 **OR**
  - For pediatric beneficiaries, weight is greater than or equal to 95th percentile (for POMC, PCSK1, or LEPR) or 97th percentile (for BBS) using growth chart assessments **AND**
- **ONE** of the following:
  - The beneficiary is newly starting therapy **OR**
  - **ONE** of the following:
    - For beneficiaries with obesity due to POMC, PCSK1, or LEPR deficiency, ONE of the following:
      - The beneficiary is currently being treated and has received less than 16 weeks (4 months) of therapy **OR**
      - The beneficiary has received at least 16 weeks of therapy, and has achieved a weight loss of **ONE** of the following:
        - Weight loss of greater than or equal to 5% of baseline body weight (prior to the initiation of the requested agent) **OR**
        - For beneficiaries with continued growth potential, weight loss of greater

than or equal to 5% of baseline BMI (prior to the initiation of the requested agent) **OR**

- For beneficiaries with obesity due to BBS, **ONE** of the following:
  - The beneficiary is currently being treated and has received less than one year of therapy **OR**
  - The beneficiary has received at least one year of therapy, and has achieved a weight loss of **ONE** of the following:
    - Weight loss of greater than or equal to 5% of baseline body weight (prior to the initiation of the requested agent) **OR**
    - For beneficiaries aged less than 18 years, weight loss of greater than or equal to 5% of baseline BMI (prior to the initiation of the requested agent) **AND**

- The beneficiary does NOT have any FDA labeled contraindications to the requested agent

Duration of Approval

- 4 months for POMC, PCSK1, or LEPR deficiency; 12 months for BBS

Renewal Criteria

- The beneficiary has been previously approved for the requested agent through the plan's Prior Authorization process [Note: beneficiaries not previously approved for the requested agent will require initial evaluation review] **AND**
- **ONE** of the following:
  - For adult beneficiaries, the beneficiary has achieved and maintained weight loss of greater than or equal to 5% of baseline body weight (prior to the initiation of the requested agent) **OR**
  - **ONE** of the following:
    - For beneficiaries with POMC, PCSK1, or LEPR deficiency **AND** continued growth potential, the beneficiary has achieved and maintained weight loss of greater than or equal to 5% of baseline BMI (prior to the initiation of the requested agent) **OR**
    - For beneficiaries with BBS **AND** are aged less than 18 years, the beneficiary has achieved and maintained weight loss of greater than or equal to 5% of baseline BMI (prior to the initiation of the requested agent) **AND**
- The beneficiary does NOT have any FDA labeled contraindications to the requested agent

Duration of Approval

- 12 months

References

1 Imcivree [package insert]. Boston, MA; Rhythm Pharmaceuticals, Inc.; December 2024

Criteria Change Log

xx/xx/xxxx	Criteria effective date