NC Medicaid
Outpatient Pharmacy Prior Approval Criteria
GLP1s for Weight Management

Effective Date: August 1, 2024

Therapeutic Class Code: J8E; J8G
Therapeutic Class Description: ANTI-OBESITY GLUCAGON-LIKE PEPTIDE-1 RECEPT.AGONIST; ANTI-OBESITY – INCRETIN MIMETICS COMBINATION

Medications
Saxenda® (liraglutide) (12 and over)
Wegovy™ (semaglutide) (12 and over)
Zepbound™ (tirzepatide) (18 and over only)

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

The beneficiary is overweight or obese and is using the requested agent for weight management and ALL of the following:

- Product prescribed must be FDA approved for the indication, age, weight (if applicable) and not exceed dosing limits per the Prescribing Information per the clinical conditions for use.
- The preferred drug, if applicable, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria, including completion of an adequate titration period of 3 to 6 months of the preferred drug. (Failure of the preferred drug is considered to be a drug trial and failure of 3 to 6 months to complete dose titration and determine the side effect profile for the member, unless there is a documented contraindication to the preferred drug. Titration can take up to 6 months for GLP1s.)
- Prescriber must provide the patient's baseline weight and BMI, to be documented on the PA form, as measured within the past 45 days of the submitted PA.
- The beneficiary is new to therapy or attempting a repeat weight loss course of therapy **AND**
- ONE of the following:
  - The beneficiary is 18 years of age or over and has ONE of the following:
    - A BMI greater than or equal to 30 kg/m^2 **OR**
    - A BMI greater than or equal to 27 kg/m^2 with at least one weight-related comorbidity/risk factor/complication (i.e. hypertension, type 2 diabetes, obstructive sleep apnea, cardiovascular disease, dyslipidemia) **OR**
  - The beneficiary is 12 - 17 years of age and has ONE of the following:
    - A BMI greater than or equal to the 95^{th} percentile for age and sex **OR**
    - A BMI greater than or equal to 30 kg/m^2 **OR**
    - A BMI greater than or equal to the 85^{th} percentile for age and sex **AND** at least one severe weight-related comorbidity/risk factor/complication **OR**
  - The beneficiary is 45 years of age or older with a BMI greater than or equal to 27 kg/m^2 **AND** has established cardiovascular disease (CVD) defined as having a history of myocardial infarction, stroke, or symptomatic peripheral disease, to be documented on the PA form. **AND**
- The beneficiary is currently on and will continue lifestyle modification including structured nutrition and physical activity, unless physical activity is not clinically appropriate at the time GLP1 therapy commences. **AND**

- The beneficiary will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND**
- The beneficiary does NOT have any FDA-labeled contraindications to the requested agent, including pregnancy, lactation, history of medullary thyroid cancer or multiple endocrine neoplasia type II.

Renewal Criteria

- The beneficiary has been previously approved for the requested agent through Medicaid's Prior Authorization process [Note: beneficiaries not previously approved for the requested agent will require initial evaluation review] **AND**
- The beneficiary is using the requested agent for weight management and ALL of the following criteria have been met:
  - The beneficiary is continuing a current weight loss course of therapy **AND**
  - Adults: the patient has lost a total of 5% of pretreatment weight and maintains the 5% weight loss. Baseline and current weight are to be provided on the PA form. **OR**
  - Adolescents: (≥12 to <18 years) have had >4% reduction in baseline BMI and maintain the weight loss. Baseline and current weight are to be provided on the PA form. OR
  - Adults or Adolescents have a documented weight loss that is deemed to be a significant reduction from BMI per the prescriber and the weight loss is maintained, yet the 5% (for adults) and 4% (for adolescents) is not met. Rationale, baseline, and current weight are to be provided on the PA form. **AND**
- The beneficiary is currently on and will continue lifestyle modification including structured nutrition and physical activity **AND**
- The beneficiary will not be using the requested agent in combination with another GLP-1 receptor agonist agent **AND**
- The beneficiary does NOT have any FDA-labeled contraindications to the requested agent

Duration of Approval

6 months for the initial approval, 12 months for renewal; no limit on the number of renewals that may be provided.

Quantity Limits

- Wegovy 3 mL/28 days. Titration doses are 2 mL/28 days.
- Saxenda 15 mL/30 days
- Zepbound 2 mL/28 days

References

1. Wegovy® [package insert]. Plainsboro, NJ: Novo Nordisk Inc. March 2024.
2. Saxenda® [package insert]. Plainsboro, NJ: Novo Nordisk Inc. June 2022
3. Zepbound™ [package insert].Indianapolis, IN: Eli Lilly USA LLC. March 2024.

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Criteria Change Log

08/01/2024	Criteria effective date