NC Medicaid
Outpatient Pharmacy Prior Approval Criteria
GLP1s ~~for Weight Management~~
Wegovy and Zepbound

Effective Date: August 1, 2024

DRAFT

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.

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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 95th 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 85th 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~~

Wegovy

1. **For the indication of cardioprotection :**
   - Beneficiary must have a documented baseline BMI prior to beginning GLP-1 therapy ≥ 27 kg/m^2 **AND**

- Beneficiary is ≥ 45 years of age **AND**
- Beneficiary must have established cardiovascular disease (CVD) defined as having a history of myocardial infarction, stroke, or symptomatic peripheral arterial disease. **AND**
- Beneficiary must **not** have a personal or family history of medullary thyroid carcinoma. **AND**
- Beneficiary must **not** have multiple endocrine neoplasia syndrome type 2. **AND**
- Beneficiary must have at least 3 months of lifestyle modifications prior to starting Wegovy. **AND**
- Beneficiary should be using Wegovy in combination with a reduced calorie diet and increased physical activity.
- 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

2. **For the indication of noncirrhotic nonalcoholic steatohepatitis (NASH) or metabolic dysfunction associated steatohepatitis (MASH)**

- The beneficiary has a diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) or metabolic dysfunction associated steatohepatitis (MASH) **AND ALL** of the following: (medical records required)
  - The beneficiary has stage F1, F2, or F3 fibrosis as confirmed by BOTH of the following (prior to therapy with the requested agent):
    - A FIB-4 score consistent with stage F1, F2, or F3 fibrosis adjusted for age **AND**
    - The beneficiary has ONE of the following:
      - A liver biopsy **OR**
      - Vibration-controlled transient elastography (VCTE) (such as FibroScan) **OR**
      - Enhanced liver fibrosis (ELF) score **OR**
      - Magnetic resonance elastography (MRE) **OR**
      - FibroSure **AND**
  - The requested agent is Wegovy **AND**
  - The beneficiary is an adult (18 years of age or over) **AND**
  - The beneficiary has ONE of the following:
    - A baseline BMI prior to beginning therapy of greater than 25 kg/ **m^2 OR**
    - A baseline BMI prior to beginning therapy of greater than 23 kg/ **m^2** if the beneficiary is of South Asian, Southeast Asian, or East Asian descent **AND**
  - The beneficiary has ONE of the following:
    - The beneficiary's sex is female then the beneficiary 's alcohol consumption is less than 20 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) **OR**
    - The beneficiary's sex is male then the beneficiary's alcohol consumption is less than 30 grams/day (Note: one standard alcoholic drink contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits) **AND**
  - The beneficiary is being monitored for development of and/or treated for any comorbid conditions (e.g., cardiovascular disease, diabetes, dyslipidemia, hypertension) **AND**

- The beneficiary does **NOT** have **ANY** of the following:
  - Decompensated cirrhosis
  - Moderate to severe hepatic impairment (Child-Pugh Class B or C)
  - Any other liver disease (e.g., Wilson's disease, hepatocellular carcinoma, hepatitis) **AND**

Wegovy Continuation Criteria (Renewal Criteria) for the indications listed above

- The beneficiary has been previously approved for the requested agent through Medicaid's Prior Authorization process for the covered indications that went into effect October 01, 2025. [Note: beneficiaries not previously approved for the requested agent will require initial evaluation review] **AND**
- Medical documentation that beneficiary has improved while on the medication **AND**
- Individual clinical goals set by the provider are being met **OR**
- Beneficiary is continuing to make adequate progress towards treatment goals. **AND**
- 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. **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
- At each renewal (reauthorization), the provider must document that a review of the beneficiary's medication list has been performed for possible dose reductions or discontinuation of medications for comorbid conditions, which are no longer needed or able to be reduced due to clinical effects of weight reduction.

Zepbound

1. For the indication of Moderate to Severe Sleep Apnea: The beneficiary is using the requested agent for moderate to severe obstructive sleep apnea (OSA) in adults with obesity and ALL of the following:

- Beneficiary must have a documented baseline BMI prior to beginning therapy of $\geq$ 30kg/ m^2 **AND**
- The beneficiary is an adult (18 years of age or over)
- 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. **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. **AND**

- Documentation confirming that sleep apnea testing was performed and moderate to severe sleep apnea was diagnosed must be submitted with the prior approval request. **AND**
- The beneficiary should have been instructed on sleep hygiene modifications before beginning Zepbound (for example, sleep positioning to avoid a non-supine position, avoidance of alcohol and stimulants before bed)

Zepbound Continuation Criteria (Renewal Criteria) for the indications listed above

- The beneficiary has been previously approved for the requested agent through Medicaid's Prior Authorization process for the covered indication that went into effect October 01, 2025. [[Note: beneficiaries not previously approved for the requested agent will require initial evaluation review] **AND**
- Medical documentation that beneficiary has improved while on the medication **AND**
- Individual clinical goals set by the provider are being met **OR**
- Beneficiary is continuing to make adequate progress towards treatment goals. **AND**
- 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. **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 **AND**
- At each renewal (reauthorization), the provider must document that a review of the beneficiary's medication list has been performed for possible dose reductions or discontinuation of medications for comorbid conditions, which are no longer needed or able to be reduced due to clinical effects of weight reduction.

Duration of Approval
6 months for initial and renewals

Quantity Limits

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

References

1. Wegovy® [package insert]. Plainsboro, NJ: Novo Nordisk Inc. March 2024; Updated August 2025.
2. Saxenda® [package insert]. Plainsboro, NJ: Novo Nordisk Inc. June 2022
3. Zepbound™ [package insert].Indianapolis, IN: Eli Lilly USA LLC. March 2024; updated December 2024. Updated April 2025.

Criteria Change Log

08/01/2024	Criteria effective date
09/30/2025	Criteria end date