

**NC Medicaid  
Outpatient Pharmacy Prior Approval Criteria  
GLP1s Wegovy and Zepbound  
Cardioprotection/NASH/MASH/OSA**

**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**

Wegovy™ (semaglutide)

Zepbound™ (tirzepatide)

**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.

**NC Medicaid  
Outpatient Pharmacy Prior Approval Criteria  
GLP1s Wegovy and Zepbound  
Cardioprotection/NASH/MASH/OSA**

**Effective Date: August 1, 2024**

**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**

**Wegovy**

**1. For the indication of cardioprotection :**

- Beneficiary must have a documented baseline BMI prior to beginning GLP-1 therapy  $\geq 27$  kg/m<sup>2</sup> **AND**
- **Beneficiary is  $\geq 45$  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**

## NC Medicaid

### Outpatient Pharmacy Prior Approval Criteria GLP1s Wegovy and Zepbound Cardioprotection/NASH/MASH/OSA

Effective Date: August 1, 2024

- 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<sup>2</sup> **OR**~~
  - ~~A baseline BMI prior to beginning therapy of greater than 23 kg/m<sup>2</sup> if the beneficiary is of South Asian, Southeast Asian, or East Asian descent **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**
- 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**~~
- **Medical documentation** that 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~~ participation in a nutrition and physical activity plan **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

**NC Medicaid  
Outpatient Pharmacy Prior Approval Criteria  
GLP1s Wegovy and Zepbound  
Cardioprotection/NASH/MASH/OSA**

**Effective Date: August 1, 2024**

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  $\geq 30\text{kg}/\text{m}^2$   
**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**

**NC Medicaid  
Outpatient Pharmacy Prior Approval Criteria  
GLP1s Wegovy and Zepbound  
Cardioprotection/NASH/MASH/OSA**

**Effective Date: August 1, 2024**

- 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.

**NC Medicaid  
Outpatient Pharmacy Prior Approval Criteria  
GLP1s Wegovy and Zepbound  
Cardioprotection/NASH/MASH/OSA**

**Effective Date: August 1, 2024**

**Criteria Change Log**

08/01/2024	Criteria effective date