NC Division of Health Benefits — Medicaid
Outpatient Pharmacy
Prior Approval Criteria
GLP-1 Receptor Agonists and Combinations — Effective Date: March 1, 2024

Therapeutic Class Code: C4I, C4X
Therapeutic Class Description: ANTIHYPERGLY,INSULIN,LONG ACT-GLP-1 RECEPT.AGONIST and Combinations

Medications	
Bydureon® Pen	Bydureon® BCise™
Byetta® Pen	Mounjaro Pen
Trulicity® Pen	Rybelsus® Tablet
Victoza® Pen	Soliqua® Injection
Ozempic® Injection	Xultophy® Injection

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

a. 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.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid Billing Guide*, sections 2 and 6, 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

Criteria for Coverage

Criteria for Initial Coverage (for both preferred and non-preferred products)

- Beneficiary must have diagnosis of Type 2 Diabetes; **AND**
- Beneficiary must have a trial and failure or insufficient response to metformin containing products OR
    - Beneficiary has a contraindication or adverse event to metformin, OR
    - Beneficiary has established ASCVD, or Chronic Kidney Disease, OR
    - Beneficiary is considered high-risk for ASCVD as defined as ≥ 55 years of age with ≥ 2 additional risk factors (smoking, obesity, hypertension, dyslipidemia, or albuminuria)
- In addition, for non-preferred products, the beneficiary must have tried and failed or experienced an insufficient response to at least two preferred products or have a clinical reason that preferred products cannot be tried

Continuation of Coverage (renewal request) for preferred and non-preferred products

- 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.

Quantity Limits

- Victoza- 4 pens per 34 days
- Trulicity- 5 pens/syringes per 34 days
- Bydureon/ Bydureon BCise - 5 pens per 34 days
- Byetta- 2 pen per 34 days
- Ozempic-
    - 0.25mg/dose, 0.5mg/dose: 2 pens per 34 days
    - 1mg/dose: 2mg prefilled pen-3 pens per 34 days

  - 4mg prefilled pen- 2 pens per 34 days
  - 2mg/dose: 2 pens per 34 days
- Xultophy-6 pens per 34 days
- Soliqua- 7 pens per 34 days
- Rybelsus Tablet- 34/34 days

Criteria to receive coverage over quantity limits- Prior approval to exceed quantity limits much include Medical and other information as it why the beneficiary needs more quantity for their course of therapy.

References

1. Byetta [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2022.
2. Bydureon [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2022.
3. Bydureon BCise [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2022.
4.Ozempic [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; March 2022.
5.Rybelsus [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; June 2022.
6. Trulicity [package insert]. Indianapolis, IN: Eli Lilly and Company; June 2022.
7. Victoza [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; June 2022.
8. Soliqua® Injection [package insert].Bridgewater, NJ: Sanofi-Aventis U.S. LLC; June 2022.
9. Xultophy® Injection [package insert]. Plainsboro, NJ: Novo Nordisk Inc. June 2022.
10. Mounjaro [package insert]. Indianapolis, IN: Lilly USA, LLC; September 2022.

Criteria Change Log

03/01/2024	Criteria effective date