Utilization Management Policy Name: GLP-1 Agonists – NC Standard

Restricted Product(s): Restriction applies to brand and generic products

- Adlyxin (lixisenatide)
- Bydureon BCise (exenatide extended release)
- Byetta (exenatide)
- Mounjaro (tirzepatide)
- Ozempic (semaglutide)
- Rybelsus (semaglutide)
- Trulicity (dulaglutide)
- Victoza (liraglutide)

FDA Approved Use:

- Adlyxin, Byetta, Mounjaro, Rybelsus
  - As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- Bydureon BCise
  - As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years and older with type 2 diabetes mellitus.
- Mounjaro
  - As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- Ozempic
  - As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus; to reduce the risk of major cardiovascular events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.
- Trulicity
  - As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus; risk reduction of major cardiovascular events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors.
- Victoza
  - As an adjunct to diet and exercise to improve glycemic control in children ≥10 years of age, adolescents, and adults with type 2 diabetes mellitus; risk reduction of major cardiovascular events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.

Criteria for Approval of Restricted Product(s):

1. The patient has a diagnosis of type 2 diabetes mellitus **(medical record documentation required)**; **AND**
    a. The request is for Ozempic, Rybelsus, Trulicity, Mounjaro or Bydureon BCise; **AND**
        i. ONE of the following:
            1. The patient has tried and had an inadequate response, intolerance, or hypersensitivity to an agent containing metformin, sulfonylurea, or insulin; **OR**
            2. The patient has an FDA labeled contraindication to metformin; **OR**
            3. The patient has a diagnosis of, or is at high risk for, atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease; **OR**
        ii. The prescriber states the patient is currently being treated with the requested agent within the past 90 days AND is at risk if therapy is changed; **OR**
    b. The request is for Adlyxin, Byetta, Victoza or liraglutide (generic Victoza); **AND**
        i. TWO of the following:
            1. The patient has tried and had an inadequate response after at least a 90 day duration of therapy, has an intolerance, has a hypersensitivity, or has an FDA labeled contraindication to semaglutide (Rybelsus OR Ozempic)
            2. The patient has tried and had an inadequate response after at least a 90 day duration of therapy, has an intolerance, has a hypersensitivity, or has an FDA labeled contraindication to dulaglutide (Trulicity)
            3. The patient has tried and had an inadequate response after at least a 90 day duration of therapy, has an intolerance, has a hypersensitivity, or has an FDA labeled contraindication to tirzepatide (Mounjaro); **AND**
        ii. ONE of the following:
            1. The patient has tried and had an inadequate response, intolerance, or hypersensitivity to an agent containing metformin, sulfonylurea or insulin; **OR**
            2. The patient has an FDA labeled contraindication to metformin; **OR**
            3. The patient has a diagnosis of, or is at high risk for, atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease; **AND**
2. The requested product will not be taken concomitantly with a DPP-4 containing agent; **AND**
3. The requested product will not be taken concomitantly with another GLP-1 agonist; **AND**
4. For formularies that exclude (non-formulary) the requested medication, Non-formulary Exception Criteria applies.

Duration of Approval: 365 days (1 year)

Quantity Limitations: quantity limitations apply to brand and associated generic products.

Medication	Quantity per Day (unless specified)
Adlyxin® (lixisenatide) 50 mcg/mL prefilled pen	2 pens every 28 days

Adlyxin® (lixisenatide) 100 mcg/mL prefilled pen	2 pens every 28 days
Bydureon BCise™ (exenatide ER) 2 mg/pen	4 pens every 28 days
Byetta® (exenatide) 5 mcg/dose prefilled pen	1 prefilled pen (60 doses) every 30 days
Byetta® (exenatide) 10 mcg/dose prefilled pen	1 prefilled pen (60 doses) every 30 days
Mounjaro™ (tirzepatide) 2.5 mg / 0.5 mL prefilled pen	2 mL (4 pens) per 180 days
Mounjaro™ (tirzepatide) 5 mg / 0.5 mL prefilled pen	2 mL (4 pens) per 28 days
Mounjaro™ (tirzepatide) 7.5 mg / 0.5 mL prefilled pen	2 mL (4 pens) per 28 days
Mounjaro™ (tirzepatide) 10 mg / 0.5 mL prefilled pen	2 mL (4 pens) per 28 days
Mounjaro™ (tirzepatide) 12.5 mg / 0.5 mL prefilled pen	2 mL (4 pens) per 28 days
Mounjaro™ (tirzepatide) 15 mg / 0.5 mL prefilled pen	2 mL (4 pens) per 28 days
Ozempic® (semaglutide) 0.25 mg or 0.5mg per dose (2mg/1.5mL) 1.5 mL, 1 pen	1 pen per 28 days
Ozempic (semaglutide) 0.25 mg or 0.5mg per dose (2mg/3mL) 3mL, 1 pen	1 pen per 28 days
Ozempic® (semaglutide) 1 mg per dose (2mg/1.5 mL) 3 mL, 2 pens	2 pens per 28 days
Ozempic® (semaglutide) 1 mg per dose (4mg/3 mL) 3 mL, 1 pen	1 pen per 28 days
Ozempic® (semaglutide) 2 mg per dose (8mg/3 mL) 3 mL, 1 pen	1 pen per 28 days
Rybelsus® (semaglutide) 3mg tablet	30 tablets per 180 days
Rybelsus® (semaglutide) 7mg tablet	1 tablet
Rybelsus® (semaglutide) 14mg tablet	1 tablet
Trulicity® (dulaglutide) 0.75 mg / 0.5 mL syringe and pens	4 pens or syringes every 28 days
Trulicity® (dulaglutide) 1.5 mg / 0.5 mL syringe and pens	4 pens or syringes every 28 days
Trulicity® (dulaglutide) 3 mg / 0.5 mL syringe and pens	4 pens or syringes every 28 days
Trulicity® (dulaglutide) 4.5 mg / 0.5 mL syringe and pens	4 pens or syringes every 28 days
Victoza® (liraglutide) 18 mg/3 mL pen; 2 pen package	3 pens every 30 days
Victoza® (liraglutide) 18 mg/3 mL pen; 3 pen package	3 pens every 30 days

Quantity Limit Exception Criteria:

1. The quantity (dose) requested is for documented titration purposes at the initiation of therapy (authorization for a 90 day titration period); **AND**
2. The prescribed dose cannot be achieved using a lesser quantity of a higher strength; **AND**
3. The quantity (dose) requested does not exceed the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert; **OR**

4. If the quantity (dose) requested exceeds the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert, then the prescriber must submit documentation in support of therapy with a higher dose for the intended diagnosis (submitted documentation may include medical records OR fax form which reflects medical record documentation that shows the length of time the requested dose has been used, and what other medications and doses have been tried and failed).

References: all information referenced is from FDA package insert unless otherwise noted below.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q1 annually.

October 2024: Criteria change: Added requirement that GLP-1s will not be taken concomitantly with a DPP-4 containing agent.
July 2024: Criteria update: Restriction applies to brand and generic products. Added new to market liraglutide (generic Victoza).
April 2024: Criteria change: Medical record documentation of Type 2 Diabetes required for approval.
January 2024: Criteria change (Victoza): Updated Victoza to require a step through two of the following: semaglutide, dulaglutide, tirzepatide.
September 2023: Criteria change: The requested product will not be taken concomitantly with another GLP-1 agonist.
April 2023: Criteria change: Added Mounjaro to policy as preferred product. Requests for Adlyxin and Byetta require a step through two of the following: semaglutide, dulaglutide, tirzepatide. Bydureon removed as product is obsolete.
January 2023: Criteria change: Rybelsus 3mg tablet QL changed to 30 tablets per 180 days. Added new to market Ozempic 2mg/3ml pen. Non-preferred GLP-1 products required to have inadequate response (90 day trials) with both semaglutide and dulaglutide.
December 2022: Criteria update: Added expanded indication for Trulicity to pediatric patients 10 years of age and older.
August 2022: Criteria update: Medical record documentation requirement removed.
July 2022: Criteria update: Medical record documentation required. Patients at high risk for atherosclerotic cardiovascular disease, heart failure, CKD not required to step through metformin/sulfonylurea/insulin.
April 2022: Criteria update: Added new 8mg/3 mL strength of Ozempic to the criteria.
July 2021: Criteria update: Added expanded indication for Bydureon to pediatric patients 10 years and older.
February 2021: Criteria update: Addition of Ozempic 4mg/3mL product to the quantity limits section.
December 2020: Criteria update: Addition of Trulicity 3.5mg and 4mg products to quantity limits section.
November: 2020: Criteria Change: A trial of preferred products was omitted from October revisions. Criteria points requiring a trial for preferred GLP1 agents prior to the use of non-preferred agents reinstated.
October 2020: Criteria update: Corrected FDA approved indications list.
October 2020: Original utilization management criteria issued.