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

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

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

FDA Approved Use:

- Bydureon BCise
  - As an adjunct to diet and exercise to improve glycemic control in adult and pediatric patients 10 years and older with type 2 diabetes mellitus.
- Byetta
  - As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- Mounjaro
  - As an adjunct to diet and exercise to improve glycemic control in adult and pediatric patients 10 years of age and older with type 2 diabetes mellitus.
  - To reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke) in adults with type 2 diabetes mellitus and who are at high risk for cardiovascular events.
- Ozempic injection
  - 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.
  - To reduce the risk of sustained eGFR decline, end-stage kidney disease, and cardiovascular death in adults with type 2 diabetes mellitus and chronic kidney disease.
- Ozempic, Rybelsus tablet
  - 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 who are at high risk for cardiovascular events.
- Trulicity
  - As an adjunct to diet and exercise to improve glycemic control in adult and pediatric patients 10 years of age and older 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 who have established cardiovascular disease or multiple cardiovascular risk factors.

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- 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.
  - 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.

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, chronic kidney disease and/or metabolic dysfunction-associated steatohepatitis (MASH); **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 Byetta, exenatide (generic 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, chronic kidney disease and/or metabolic dysfunction-associated steatohepatitis (MASH); **AND**

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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)
Bydureon BCise (exenatide ER) 2 mg/pen	3.4 mL (4 pens) per 28 days
Byetta (exenatide) 5 mcg/dose prefilled pen	1.2 mL (1 pen) per 30 days
Byetta (exenatide) 10 mcg/dose prefilled pen	2.4 mL (1 pen) per 30 days
Mounjaro (tirzepatide) 2.5 mg/0.5 mL prefilled pen	2 mL (4 pens) per 28 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/3mL) pen	3 mL (1 pen) per 28 days
Ozempic (semaglutide) 1 mg per dose (4mg/3 mL) pen	3 mL (1 pen) per 28 days
Ozempic (semaglutide) 2 mg per dose (8mg/3 mL) pen	3 mL (1 pen) per 28 days
Ozempic, Rybelsus (semaglutide) 1.5mg tablet	1 tablet
Rybelsus (semaglutide) 3mg tablet	1 tablet
Ozempic, Rybelsus (semaglutide) 4mg tablet	1 tablet
Rybelsus (semaglutide) 7mg tablet	1 tablet
Ozempic, Rybelsus (semaglutide) 9mg tablet	1 tablet
Rybelsus (semaglutide) 14mg tablet	1 tablet
Trulicity (dulaglutide) 0.75 mg/0.5 mL pen	2 mL (4 pens) per 28 days
Trulicity (dulaglutide) 1.5 mg/0.5 mL pen	2 mL (4 pens) per 28 days
Trulicity (dulaglutide) 3 mg/0.5 mL pen	2 mL (4 pens) per 28 days
Trulicity (dulaglutide) 4.5 mg/0.5 mL pen	2 mL (4 pens) per 28 days
Victoza (liraglutide) 18 mg/3 mL pen; 2 pen package	9mL (3 pens) per 30 days

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Victoza (liraglutide) 18 mg/3 mL pen; 3 pen package	9mL (3 pens) per 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).

Duration of Approval: 365 days (1 year)

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.

September 2026: Criteria update: Added expanded indication for Mounjaro for risk reduction of major cardiovascular events in adults with type 2 diabetes and who are at risk for cardiovascular events.
May 2026: Criteria update: Added new to market Ozempic tablets to policy.
Jan 2026: Criteria update: Added expanded indication for Mounjaro to pediatric patients 10 years of age and older.
Nov 2025: Criteria update: Added expanded indication for Rybelsus for risk reduction of major cardiovascular events in adults with type 2 diabetes and who are at risk for cardiovascular events.
Nov 2025: Criteria change: Removed obsolete Adlyxin. Patients with MASH not required to step through metformin/sulfonylurea/insulin. Updated Mounjaro 2.5mg/0.5mL QL to 4 pens per 28 days and Rybelsus 1.5mg and 3mg QL to 1 tablet per day.
April 2025: Criteria update: Added new to market exenatide (generic Byetta) to policy.
March 2025: Criteria update: Addition of Rybelsus 1.5mg, 4mg, and 9mg products to quantity limits section.
Feb 2025: Criteria update: Added expanded indication for Ozempic in patients with type 2 diabetes and chronic kidney disease.
Oct 2024: Criteria change: Added requirement that GLP-1s will not be taken concomitantly with a DPP-4 containing agent.

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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.
Jan 2024: Criteria change (Victoza): Updated Victoza to require a step through two of the following: semaglutide, dulaglutide, tirzepatide.
Sept 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.
Jan 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.
Historical policy changes prior to 2023 can be obtained from BCBSNC Corporate Pharmacy

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