PRIOR AUTHORIZATION CRITERIA

DRUG CLASS
BRAND NAME
(generic)

GLUCAGON-LIKE PEPTIDE-1 (GLP-1) RECEPTOR AGONIST:

ADLYXIN
(lixisenatide)

BYDUREON BCISE
(exenatide extended-release)

BYETTA
(exenatide)

OZEMPIC
(semaglutide)

RYBELSUS
(semaglutide)

TRULICITY
(dulaglutide)

VICTOZA
(liraglutide)

GLUCOSE-DEPENDENT INSULINOTROPIC POLYPEPTIDE (GIP) RECEPTOR AND GLUCAGON-LIKE PEPTIDE-1 (GLP-1) RECEPTOR AGONIST:

MOUNJARO
(tirzepatide)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization with Logic

POLICY

FDA APPROVED INDICATIONS

GLP-1 RECEPTOR AGONIST:

Adlyxin

Adlyxin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

- Adlyxin has not been studied in patients with chronic pancreatitis or a history of unexplained pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Adlyxin should not be used in patients with type 1 diabetes mellitus.

- Adlyxin has not been studied in patients with gastroparesis and is not recommended in patients with gastroparesis.

Bydureon BCise
Bydureon BCise is indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus.

Limitations of Use:
- Bydureon BCise is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of the rat thyroid C-cell tumor findings to humans.
- Bydureon BCise is not indicated for use in patients with type 1 diabetes mellitus.
- Bydureon BCise is an extended-release formulation of exenatide and should not be used with other products containing the active ingredient exenatide.
- Bydureon BCise has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.

Byetta
Byetta is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use
- Byetta is not indicated for use in patients with type 1 diabetes.
- Byetta contains exenatide and should not be used with other products containing the active ingredient exenatide. Byetta has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.

Ozempic
Ozempic is indicated:
- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.

Limitations of Use
- Ozempic has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Ozempic is not indicated for use in patients with type 1 diabetes mellitus.

Rybelsus
Rybelsus is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use
- Rybelsus has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Rybelsus is not indicated for use in patients with type 1 diabetes mellitus.

Trulicity
Trulicity is indicated:
- 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.
- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors.

Limitations of Use

- Trulicity has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Trulicity should not be used in patients with type 1 diabetes mellitus.
- Trulicity has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis and is therefore not recommended in these patients.

Victoza
Victoza is indicated:
- as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus.
- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.

Limitations of Use
- Victoza should not be used in patients with type 1 diabetes mellitus.
- Victoza contains liraglutide and should not be coadministered with other liraglutide-containing products.

GIP/GLP-1 RECEPTOR AGONIST:
Mounjaro
Mounjaro is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Limitations of Use
- Mounjaro has not been studied in patients with a history of pancreatitis.
- Mounjaro is not indicated for use in patients with type 1 diabetes mellitus.

SCREEN OUT LOGIC*
**Include Rx and OTC products unless otherwise stated.*

If a claim is submitted with an ICD 10 diagnosis code indicating type 2 diabetes mellitus under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.

For patients with no ICD 10 diagnosis code indicating type 2 diabetes mellitus submitted with their prescription claim:
If the patient has filled a prescription for at least a 30-day supply of a diabetic supply (EXCLUDING insulin pen needles and insulin syringes) OR metformin when the date of a metformin fill is AT LEAST 10 days prior to the claim for the requested drug OR another antidiabetic drug (EXCLUDING all target drugs) within the past 730 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial screen out logic, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA

Type 2 Diabetes Mellitus
Authorization may be granted when the patient has a diagnosis of type 2 diabetes mellitus when ONE of the following criteria are met:
- The patient has a history of an A1C greater than or equal to 6.5 percent. [ACTION REQUIRED: Documentation is required for approval.]
- The patient has a history of a 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test (OGTT). [ACTION REQUIRED: Documentation is required for approval.]
- The patient has a history of symptoms of hyperglycemia (e.g., polyuria, polydipsia, polyphagia) or hyperglycemic crisis and a random plasma glucose greater than or equal to 200 mg/dL. [ACTION REQUIRED: Documentation is required for approval.]

- The patient has a history of a fasting plasma glucose (FPG) greater than or equal to 126 mg/dL [ACTION REQUIRED: Documentation is required for approval.] when the following criteria is met:
    - The patient fasted for at least 8 hours prior to the fasting plasma glucose (FPG) greater than or equal to 126 mg/dL

DURATION OF APPROVAL (DOA)

- 5694-D: DOA: 36 months

REFERENCES

1. Adlyxin [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; June 2022.
2. Bydureon BCise [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2023.
3. Byetta [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2022.
4. Mounjaro [package insert]. Indianapolis, IN: Lilly USA, LLC; July 2023.
5. Ozempic [package insert]. Plainsboro, NJ: Novo-Nordisk Inc.; September 2023.
6. Rybelsus [package insert]. Plainsboro, NJ: Novo-Nordisk Inc.; January 2024.
7. Trulicity [package insert]. Indianapolis, IN: Eli Lilly and Company; December 2022.
8. Victoza [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; July 2023.
9. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed March 11, 2024.
10. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 03/11/2024).
11. Blonde L, Umpierrez GE, Reddy SS et. al. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan – 2022 Update. Endocr Pract. 2022;28(10):923-1049.
12. Davies MJ, Aroda VR, Collins BS, et. al. Management of Hyperglycemia in Type 2 Diabetes, 2022. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care. 2022;45(11):2753-2786.
13. American Diabetes Association Professional Practice Committee. American Diabetes Association, Standards of Care in Diabetes – 2024. Diabetes Care. 2024;47(Suppl. 1):S1-S322.
14. Samson SL, Vellank P, Blonde L, et. Al. American Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm 2023 Update. Endocr Pract. 2023; 29: 305-340.