ANTIDIABETIC GLP-1 RECEPTOR AGONISTS & GIP/GLP-1 RECEPTOR AGONISTS

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Antidiabetic GLP-1 Receptor Agonists & GIP/GLP-1 Receptor Agonists policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. For this program, Mounjaro, Ozempic, Trulicity, and Victoza are the preferred products. The criteria will require the use of the health plan's preferred products before the use of the targeted products, Bydureon BCise, Byetta, and Adlyxin, unless there are clinical circumstances that exclude the use of the preferred products. The indications below are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

Note: Drugs used for weight reduction and management, including antidiabetic drugs used off-label, are a standard exclusion for most benefits. Benefits are subject to the terms and conditions of the member's contract. Please contact Wellmark customer service at the number on the member's ID card with benefit questions.

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 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 extended-release formulations 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 patients 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.

POLICY

SCREEN OUT LOGIC

If a claim is submitted with an ICD 10 diagnosis code indicating type 2 diabetes mellitus under the member's pharmacy benefit, then the requested drug will be paid under that pharmacy benefit.

If a claim is submitted with an ICD 10 diagnosis code other than type 2 diabetes mellitus under the member's pharmacy benefit, the requested drug will reject as not a covered pharmacy benefit.

If the member 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.

Note: If the PA is submitted indicating a diagnosis of obesity or overweight, the requested drug will be denied as not a covered pharmacy benefit.

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Type 2 diabetes mellitus

1. For initial requests: Chart notes or medical record documentation supporting a diagnosis of type 2 diabetes mellitus (i.e., A1C greater than 6.5 percent, 2-hour plasma glucose greater

than or equal to 200 mg/dL during oral glucose tolerance test (OGTT), 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, or a history of a fasting plasma glucose (FPG) greater than or equal to 126 mg/dL)

Must meet BOTH the Preferred Drug Plan Design and Coverage Criteria when both are applicable.

Preferred Drug Plan Design

A) Type 2 diabetes mellitus

1. Criteria for initial approval for Bydureon BCise, Byetta, and Adlyxin will only apply when the following criteria are met:
   a) Member has had an inadequate response to treatment or intolerable adverse event with ALL of the preferred products, Mounjaro, Ozempic, Trulicity, and Victoza

Coverage Criteria

A. Type 2 diabetes mellitus

1. Authorization of 12 months may be granted for Antidiabetic GLP-1 Receptor Agonists & GIP/GLP-1 Receptor Agonists in this policy when the diagnosis of type 2 diabetes mellitus is confirmed by any of the following:
   a. The member has a history of an A1C greater than or equal to 6.5 percent
   b. The member has a history of a 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test (OGTT)
   c. The member 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
   d. The member has a history of a fasting plasma glucose (FPG) greater than or equal to 126 mg/dL

The aforementioned drugs are considered **not a covered benefit** for patients who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Adlyxin – 2 pens/28 days
Bydureon BCise – 4 autoinjectors/28 days
Byetta – 1 pen/28 days
Ozempic – 1 pen/28 days
Rybelsus – 30 tablets/30 days
Trulicity – 4 pens/28 days
Victoza – 3 pens/28 days
Mounjaro – 4 pens/28 days

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Adlyxin (lixisenatide), Bydureon BCise (exenatide extended-release), Byetta (exenatide), Mounjaro (tirzepatide), Ozempic (semaglutide), Rybelsus (semaglutide), Trulicity (dulaglutide), and Victoza (liraglutide) are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. Trulicity, Victoza and

Bydureon BCISE are also indicated as adjuncts to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus.

Diabetes may be diagnosed based on plasma glucose criteria, either the fasting plasma glucose (FPG) value or the 2-hour plasma glucose (2-h PG) value during a 75-g oral glucose tolerance test (OGTT) or A1C criteria. FPG ≥ 126 mg/dL (after ≥ 8 hours of an overnight fast), 2-hour PG ≥ 200 mg/dL during 75-g OGTT, and A1C ≥ 6.5% are equally appropriate for diagnostic screening. Additionally, symptoms of hyperglycemia (e.g., polyuria, polydipsia, polyphagia) or hyperglycemic crisis and a random plasma glucose ≥ 200 mg/dL will confirm a diagnosis of diabetes.

Note: Drugs used for weight reduction and management, including antidiabetic drugs used off-label, are a standard exclusion for most benefits. Benefits are subject to the terms and conditions of the member's contract. Please contact Wellmark customer service at the number on the member's ID card with benefit questions.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

REFERENCES

- Adlyxin [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; June 2022.
- Bydureon BCise [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2022.
- Byetta [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2022.
- Mounjaro [package insert]. Indianapolis, IN: Lilly USA, LLC.; September 2022.
- Ozempic [package insert]. Plainsboro, NJ: Novo-Nordisk Inc.; October 2022.
- Rybelsus [package insert]. Plainsboro, NJ: Novo-Nordisk Inc.; January 2023.
- Trulicity [package insert]. Indianapolis, IN: Eli Lilly and Company; November 2022.
- Victoza [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; June 2022.
- Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2022; Accessed December 7, 2022.
- Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed December 7, 2022.
- El Sayed NA, Aleppo G, Aroda VR et. al. American Diabetes Association, Standards of Care in Diabetes – 2023. Diabetes Care 2023;46(Suppl. 1):S1-S291.
- 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. Endocrine Practice 28 (2022) 923-1049.

POLICY HISTORY

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