

**Subject: Antidiabetic GLP-1, GIP-GLP-1 Agonist Limit Policy 4525-H 05-2023**

**Drug**  
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*)

**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 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.

**INITIAL LIMIT QUANTITY**

**Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength.**

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

<b>Drug</b>	<b>Maximum Dosing</b>	<b>Package Size(s)</b>	<b>1 Month Limit* 3 Months Limit*</b>
Adlyxin	20mcg daily	Starter pack - 2 pens (1 pen of 10mcg, 1 pen of 20mcg), 14 doses per pen, 3mL each Maintenance pack - 2 pens of 20mcg, 14 doses per pen, 3mL each	2 prefilled pens (6mL) / 21 days 6 prefilled pens (18mL) / 63 days
Bydureon BCISE	2mg once weekly	Carton of 4 single-dose autoinjectors (2mg/0.85mL each)	4 auto-injectors (3.4mL) / 21 days 12 auto-injectors (10.2mL) / 63 days
Byetta	10mcg twice daily	5mcg dose, 60 doses, 1.2mL prefilled pen 10mcg dose, 60 doses, 2.4mL prefilled pen	1 prefilled pen (1.2mL) / 25 days 3 prefilled pens (3.6mL) / 75 days 1 prefilled pen (2.4mL) / 25 days 3 prefilled pens (7.2mL) / 75 days
Mounjaro	15mg once weekly	2.5mg/0.5mL, 5mg/0.5mL, 7.5mg/0.5mL, 10mg/0.5mL, 12.5mg/0.5mL, 15mg/0.5mL in cartons of 4 single-dose pens (0.5mL each) Carton of 1 pen (2mg/1.5mL)	4 pens (2mL) / 21 days 12 pens (6mL) / 63 days 1 prefilled pen (1.5mL) / 21 days 3 prefilled pens (4.5mL) / 63 days
Ozempic	2mg once weekly	Carton of 1 pen (2mg/3mL) Carton of 1 pen (4mg/3mL) Carton of 1 pen (8mg/3mL)	1 prefilled pen (3mL) / 21 days 3 prefilled pens (9mL) / 63 days 1 prefilled pen (3mL) / 21 days 3 prefilled pens (9mL) / 63 days 1 prefilled pen (3mL) / 21 days 3 prefilled pens (9mL) / 63 days
Rybelsus	14mg once daily	3mg, 7mg, 14mg in bottles of 30 tablets	30 tablets / 25 days 90 tablets / 75 days
Trulicity	4.5mg once weekly	0.75mg/0.5mL, 1.5mg/0.5mL, 3mg/0.5mL, 4.5mg/0.5mL in cartons of 4 single-dose pens (0.5mL each)	4 pens (2mL) / 21 days 12 pens (6mL) / 63 days
Victoza	1.8mg once daily	Package of 2 or 3 pens (18mg/3mL each)	3 pens (9mL) / 25 days 9 pens (27mL) / 75 days

\*The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing OR the duration of 21 days is used for a 28-day fill period and 63 days is used for an 84-day fill period to allow time for refill processing.

**Place of Service:**

Outpatient

**The above policy is based on the following references:**

1. Adlyxin [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; June 2022.

2. Bydureon BCise [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2022.
3. Byetta [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2022.
4. Mounjaro [package insert]. Indianapolis, IN: Lilly USA, LLC; September 2022.
5. Ozempic [package insert]. Plainsboro, NJ: Novo-Nordisk Inc.; October 2022.
6. Rybelsus [package insert]. Plainsboro, NJ: Novo-Nordisk Inc.; December 2022.
7. Trulicity [package insert]. Indianapolis, IN: Eli Lilly and Company; December 2022.
8. Victoza [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; June 2022.

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