

# 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: Client Requested Criteria**

**Type: Initial Prior Authorization with Logic**

**Ref # C25460-D**

*\* Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

### **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.

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### 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:

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- 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.

#### **SCREEN OUT LOGIC**

If the patient has an ICD 10 diagnosis code indicating type 2 diabetes mellitus in their member profile, 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**

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has a diagnosis of type 2 diabetes mellitus [NOTE: The prescriber MUST submit chart notes documenting a diagnosis of type 2 diabetes mellitus, including a diagnosis code consistent with type 2 diabetes mellitus (e.g., E11.x).]

#### **AND**

- Recent chart notes from the past 18 months documenting a diagnosis of type 2 diabetes mellitus, including diagnosis code, have been submitted to CVS Health

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## **RATIONALE**

If the patient has an ICD 10 diagnosis code indicating type 2 diabetes mellitus in their member profile, 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.

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.

## **REFERENCES**

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