

## STEP THERAPY CRITERIA

**DRUG CLASS**

**DIPEPTIDYL PEPTIDASE-4 (DPP-4) INHIBITORS**

**BRAND NAME  
(generic)**

**JANUMET  
(sitagliptin/metformin)**

**JANUMET XR  
(sitagliptin/metformin extended-release)**

**JANUVIA  
(sitagliptin)**

**JENTADUETO  
(linagliptin/metformin)**

**JENTADUETO XR  
(linagliptin/metformin extended-release)**

**KAZANO  
(alogliptin/metformin)**

**KOMBIGLYZE XR  
(saxagliptin/metformin extended-release)**

**NESINA  
(alogliptin)**

**ONGLYZA  
(saxagliptin)**

**OSENI  
(alogliptin/pioglitazone)**

**TRADJENTA  
(linagliptin)**

**Status: CVS Caremark Criteria**

**Type: Initial Step Therapy; Post Step Therapy Prior Authorization**

**POLICY**

DPP-4 Inhibitors Step Therapy Policy 07-2017

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## **FDA-APPROVED INDICATIONS**

### **Janumet**

Janumet is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both sitagliptin and metformin is appropriate.

Important Limitations of Use:

- Janumet should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.
- Janumet has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using Janumet.

### **Janumet XR**

Janumet XR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both sitagliptin and metformin extended-release is appropriate.

Important Limitations of Use:

- Janumet XR should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.
- Janumet XR has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using Janumet XR.

### **Januvia**

#### **Monotherapy and Combination Therapy**

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

Important Limitations of Use:

- Januvia should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.
- Januvia has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using Januvia.

### **Jentadueto**

Jentadueto is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate.

Important Limitations of Use:

- Jentadueto should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.
- Jentadueto has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using Jentadueto.

### **Jentadueto XR**

Jentadueto XR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate.

Important Limitations of Use:

- Jentadueto XR should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings
- Jentadueto XR has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using Jentadueto XR

### **Kazano**

#### **Monotherapy and Combination Therapy**

Kazano is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both alogliptin and metformin is appropriate.

Important Limitations of Use:

- Kazano should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.

### **Kombiglyze XR**

Kombiglyze XR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both saxagliptin and metformin is appropriate.

Important Limitations of Use:

- Kombiglyze XR should not be used for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.

### **Nesina**

#### Monotherapy and Combination Therapy

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

Important Limitations of Use:

- Nesina should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.

### **Onglyza**

#### Monotherapy and Combination Therapy

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

Important Limitations of Use:

- Onglyza should not be used for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis, as it would not be effective in these settings.

### **Oseni**

Oseni is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both alogliptin and pioglitazone is appropriate.

Limitation of Use:

- Oseni should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.

### **Tradjenta**

#### Monotherapy and Combination Therapy

Tradjenta tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Important Limitations of Use:

- Tradjenta should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.
- Tradjenta has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using Tradjenta.

### **INITIAL STEP THERAPY**

If the patient has filled a prescription for a 30 day supply of metformin within the past 180 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 step therapy criteria, then the system 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:

- Patient has been receiving the requested drug for at least 3 months AND demonstrated a reduction in A1c (hemoglobin A1c) since starting this therapy

**OR**

- Patient has the diagnosis of type 2 diabetes mellitus

**AND**

- Patient has experienced an inadequate treatment response, intolerance, or contraindication to metformin

**OR**

- Patient requires combination therapy AND has an A1c (hemoglobin A1c) of 7.5 percent or greater

## **REFERENCES**

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