

## PRIOR AUTHORIZATION CRITERIA

<b>DRUG CLASS</b>	<b>DIPEPTIDYL PEPTIDASE-4 (DPP-4) INHIBITORS</b>
<b>BRAND NAME (generic)</b>	<p><b>JANUMET (sitagliptin/metformin)</b></p> <p><b>JANUMET XR (sitagliptin/metformin extended-release)</b></p> <p><b>JANUVIA (sitagliptin)</b></p> <p><b>JENTADUETO (linagliptin/metformin)</b></p> <p><b>JENTADUETO XR (linagliptin/metformin extended-release)</b></p> <p><b>KAZANO (alogliptin/metformin)</b></p> <p><b>KOMBIGLYZE XR (saxagliptin/metformin extended-release)</b></p> <p><b>NESINA (alogliptin)</b></p> <p><b>ONGLYZA (saxagliptin)</b></p> <p><b>OSENI (alogliptin/pioglitazone)</b></p> <p><b>TRADJENTA (linagliptin)</b></p>
<b>Status: CVS Caremark Criteria</b>	
<b>Type: Initial Prior Authorization</b>	

DPP-4 Inhibitors Policy 673-A 07-2017

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## **POLICY**

### **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.

## **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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