

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)****ZITUVIMET
(sitagliptin/metformin)****ZITUVIO
(sitagliptin)****Status: CVS Caremark[®] Criteria**

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POLICY

FDA-APPROVED INDICATIONS

Janumet/Janumet XR

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

Limitations of Use

- Janumet/Janumet XR should not be used in patients with type 1 diabetes mellitus.
- Janumet/Janumet XR have 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.

Januvia

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

Limitations of Use:

- Januvia should not be used in patients with type 1 diabetes.
- 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 XR

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

Limitations of Use:

- Jentadueto/Jentadueto XR should not be used in patients with type 1 diabetes.
- Jentadueto/Jentadueto XR have 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.

Kazano

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

Limitations of Use:

- Kazano should not be used in patients with type 1 diabetes mellitus.

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.

Limitations of Use:

- Kombiglyze XR is not indicated for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.

Nesina

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

Limitations of Use:

- Nesina should not be used in patients with type 1 diabetes mellitus.

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.

Limitations of Use:

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- Onglyza is not indicated 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.

Limitations of Use:

- Oseni should not be used in patients with type 1 diabetes mellitus.

Tradjenta

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

Limitations of Use:

- Tradjenta should not be used in patients with type 1 diabetes as it would not be effective.
- 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.

Zituvimet

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

Limitations of Use:

Zituvimet is not recommended in patients with type 1 diabetes mellitus.

Zituvimet 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 Zituvimet.

Zituvio

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

Limitations of Use:

Zituvio is not recommended in patients with type 1 diabetes mellitus.

Zituvio 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 Zituvio.

INITIAL STEP THERAPY

**Include Rx and OTC products unless otherwise stated.*

If the patient has filled a prescription for at least 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 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 **AND**
 - The patient has NOT been receiving a stable maintenance dose of the requested drug for at least 3 months **AND**
 - The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to metformin
 - OR**
 - The patient requires combination therapy **AND** has an A1C of 7.5 percent or greater
- OR**
 - The patient has been receiving a stable maintenance dose of the requested drug for at least 3 months **AND**

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- The patient has demonstrated a reduction in A1C since starting this therapy

Duration of Approval (DOA):

- 1009-D: DOA: 36 months

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