

# 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)
	ZITUVIMET XR (sitagliptin/metformin extended-release)
	ZITUVIO

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(sitagliptin)

**Status: CVS Caremark® Criteria**

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

**Ref # 1009-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**

#### **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**

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### 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:

- 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 XR**

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

#### Limitations of Use:

Zituvimet/Zituvimet XR are not recommended in patients with type 1 diabetes mellitus.

Zituvimet/Zituvimet 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 Zituvimet/Zituvimet XR.

### **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**

#### **Type 2 Diabetes Mellitus**

Authorization may be granted for a diagnosis of type 2 diabetes mellitus when the following criteria is met:

- The patient has NOT been receiving a stable maintenance dose of the requested drug for at least 3 months and ONE of the following criteria are met:

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- The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to metformin
- The patient requires combination therapy AND has an A1C of 7.5 percent or greater

## **CONTINUATION OF THERAPY**

### **Type 2 Diabetes Mellitus**

Authorization may be granted for a diagnosis of type 2 diabetes mellitus when the following criteria is met:

- The patient has been receiving a stable maintenance dose of the requested drug for at least 3 months and the following criteria is met:
  - The patient has demonstrated a reduction in A1C since starting this therapy

## **DURATION OF APPROVAL (DOA)**

- 1009-D: DOA: 36 months

## **REFERENCES**

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Written by: UM Development (MS)

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Reviewed: Medical Affairs (DC) 07/2013; (AD) 07/2014; (DNC) 07/2015; (ME) 07/2016, 07/2017; (CHART) 08/01/2019, 07/30/2020, (CHART) 08/05/2021, 07/28/2022, 04/27/2023, 11/16/2023, 04/25/2024, 08/01/2024  
External Review: 10/2013, 10/2014, 10/2015, 10/2016, 10/2017, 10/2018, 10/2019, 10/2020, 10/2021, 10/2022, 08/2023, 12/2023 (FYI), 09/2024 (FYI), 09/2024

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**CRITERIA FOR APPROVAL**

1	Does the patient have a diagnosis of type 2 diabetes mellitus? [If Yes, then go to 2. If No, then no further questions.]	Yes	No
2	Has the patient been receiving a stable maintenance dose of the requested drug for at least 3 months? [If Yes, then go to 3. If No, then go to 4.]	Yes	No
3	Has the patient demonstrated a reduction in A1C since starting this therapy? [No further questions]	Yes	No
4	Has the patient experienced an inadequate treatment response, intolerance, or does the patient have a contraindication to metformin? [If Yes, then no further questions. If No, then go to 5.]	Yes	No
5	Does the patient require combination therapy AND have an A1C of 7.5 percent or greater? [No further questions]	Yes	No

Mapping Instructions			
	Yes	No	DENIAL REASONS
1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for type 2 diabetes. Your plan does not cover the drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Diagnosis]
2.	Go to 3	Go to 4	
3.	Approve, 36 Months	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Continuation: Efficacy]
4.	Approve, 36 Months	Go to 5	
5.	Approve, 36 Months	Deny	Your plan only covers this drug when: A) You have tried metformin, and it did not work well for you, or B) Your A1C is in a certain range (A1C greater than or equal to 7.5 percent) and you need more than one drug for your condition. We reviewed information we had. Your request has been denied because: A) You have not tried metformin, B) You do not have a medical reason not to

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			<p>take metformin, or C) Your A1C results were not in the approvable range. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Step therapy – metformin, lab/test]</p>
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