

# Step Therapy Criteria

## Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Brynovin	sitagliptin
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	sitagliptin

### Indications

#### FDA-Approved Indications

Reference number(s)
1009-D

## Brynovin

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

### Limitations of Use

- Brynovin is not recommended in patients with type 1 diabetes.
- Brynovin 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 Brynovin.

## 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.

Reference number(s)
1009-D

### **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**

- 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.

Reference number(s)
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## Zituvimet/Zituvimet XR

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/Zituvimet XR is not recommended in patients with type 1 diabetes mellitus.
- Zituvimet/Zituvimet 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 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 is met:
  - 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

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# 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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7. Kazano [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; July 2023.
8. Kombiglyze XR [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2019.
9. Nesina [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; July 2023.
10. Onglyza [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2019.
11. Oseni [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; December 2023.
12. Tradjenta [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; April 2022.
13. Zituvimet [package insert]. Pennington, NJ: Zydus Pharmaceuticals (USA) Inc.; November 2023.
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20. American Diabetes Association Professional Practice Committee. American Diabetes Association, Standards of Care in Diabetes – 2024. *Diabetes Care*. 2024;47(Suppl. 1):S1-S322.
21. Samson SL, Vellank P, Blonde L, et. Al. American Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm 2023 Update. *Endocr Pract*. 2023; 29: 305-340.