

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
alogliptin (brand unavailable)	alogliptin
alogliptin/metformin (brand unavailable)	alogliptin/metformin
alogliptin/pioglitazone (brand unavailable)	alogliptin/pioglitazone
Brynovin	sitagliptin
Janumet	sitagliptin/metformin
Janumet XR	sitagliptin/metformin extended-release
Januvia	sitagliptin
Jentadueto	linagliptin/metformin
Jentadueto XR	linagliptin/metformin extended-release
Onglyza	saxagliptin
saxagliptin/metformin extended-release (brand unavailable)	saxagliptin/metformin extended-release
Sitagliptin	sitagliptin
Sitagliptin/metformin	sitagliptin/metformin
Sitagliptin/metformin extended release	sitagliptin/metformin extended release
Tradjenta	linagliptin
Zituvimet	sitagliptin/metformin
Zituvimet XR	sitagliptin/metformin extended release
Zituvio	sitagliptin

Indications

FDA-approved Indications

Alogliptin

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

Limitations of Use

- Alogliptin tablet is not recommended for use in patients with type 1 diabetes mellitus.

Alogliptin-metformin

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

Limitations of Use

- Alogliptin and metformin HCl tablets are not recommended for use in patients with type 1 diabetes mellitus.

Alogliptin-pioglitazone

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

Limitations of Use

- Alogliptin and pioglitazone tablets should not be used in patients with type 1 diabetes mellitus.

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.

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.

Saxagliptin-metformin extended-release

Saxagliptin and metformin hydrochloride extended-release tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

- Saxagliptin and metformin hydrochloride extended-release tablets are not recommended for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.

Sitagliptin

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

Limitations of Use

- Sitagliptin tablets are not recommended in patients with type 1 diabetes mellitus.
- Sitagliptin tablets 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 Sitagliptin tablets.

Sitagliptin-metformin/Sitagliptin-metformin extended-release

Sitagliptin-metformin hydrochloride/Sitagliptin-metformin hydrochloride extended-release tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

- Sitagliptin-metformin hydrochloride/Sitagliptin-metformin hydrochloride extended-release tablets are not recommended in patients with type 1 diabetes mellitus.
- Sitagliptin-metformin hydrochloride/Sitagliptin-metformin hydrochloride extended-release tablets 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 Sitagliptin-metformin hydrochloride/Sitagliptin-metformin hydrochloride extended-release tablets.

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 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.

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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3. Alogliptin and pioglitazone [package insert]. Minneapolis, MN: Padagis.; June 2025.
4. Brynovin [package insert]. Woburn, MA: Azurity Pharmaceuticals, Inc.; January 2025.
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6. Janumet XR [package insert]. Rahway, NJ: Merck Sharp & Dohme Corp; July 2022.
7. Januvia [package insert]. Rahway, NJ: Merck Sharp & Dohme LLC; July 2023.
8. Jentadueto [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; June 2023.
9. Jentadueto XR [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; June 2023.
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14. Sitagliptin and metformin hydrochloride extended-release [package insert]. Pennington, NJ: Zydus Pharmaceuticals (USA) Inc.; August 2024.
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21. Blonde L, Umpierrez GE, Reddy SS et. Al. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan – 2022 Update. *Endocr Pract.* 2022;28(10):923-1049.
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Reference number(s)
1009-D

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