

Subject: DPP-4 Inhibitors ST, Post PA Policy 1009-D UDR 05-2024

Drug

DIPEPTIDYL PEPTIDASE-4 (DPP-4) INHIBITORS

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*)

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

Monootherapy 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:
 - 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

Place of Service:

Outpatient

The above policy is based on the following references:

1. Janumet [package insert]. Rahway, NJ: Merck Sharp & Dohme LLC; July 2022.
2. Janumet XR [package insert]. Rahway, NJ: Merck Sharp & Dohme Corp; July 2022.
3. Januvia [package insert]. Rahway, NJ: Merck Sharp & Dohme LLC; July 2023.
4. Jentadueto [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; June 2023.
5. Jentadueto XR [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; June 2023.
6. Kazano [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; July 2023.
7. Kombiglyze XR [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2019.
8. Nesina [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; July 2023.
9. Onglyza [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2019.
10. Oseni [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; December 2023.
11. Tradjenta [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; April 2022.
12. Zituvimet [package insert]. Pennington, NJ: Zydus Pharmaceuticals (USA) Inc.; November 2023.
13. Zituvimet XR [package insert]. Pennington, NJ: Zydus Pharmaceuticals (USA) Inc.; July 2024.
14. Zituvio [package insert]. Pennington, NJ: Zydus Pharmaceuticals (USA) Inc.; November 2023.
15. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed March 11, 2024.
16. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 03/11/2024).
17. 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.
18. Davies MJ, Aroda VR, Collins BS, et. al. Management of Hyperglycemia in Type 2 Diabetes, 2022. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care.* 2022;45(11):2753-2786.
19. American Diabetes Association Professional Practice Committee. American Diabetes Association, Standards of Care in Diabetes – 2024. *Diabetes Care.* 2024;47(Suppl. 1):S1-S322.
20. 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.

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October 27, 2024