

STEP THERAPY CRITERIA

DRUG CLASS	DIPEPTIDYL PEPTIDASE-4 (DPP-4) INHIBITORS
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BRAND NAME (generic)	
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	JANUMET (sitagliptin/metformin)
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	JANUMET XR (sitagliptin/metformin extended-release)
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	JANUVIA (sitagliptin)
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	JENTADUETO (linagliptin/metformin)
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	JENTADUETO XR (linagliptin/metformin extended-release)
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	KAZANO (alogliptin/metformin)
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	KOMBIGLYZE XR (saxagliptin/metformin extended-release)
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	NESINA (alogliptin)
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	ONGLYZA (saxagliptin)
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	OSENI (alogliptin/pioglitazone)
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	TRADJENTA (linagliptin)
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Status: CVS Caremark Criteria

Type: Initial Step Therapy; Post Step Therapy Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Janumet

Janumet is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both sitagliptin and metformin is appropriate.

DPP-4 Inhibitors Step Therapy Policy 1009-D 07-2017

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Important Limitations of Use:

- Janumet should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.
- Janumet 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 Janumet.

Janumet XR

Janumet 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 sitagliptin and metformin extended-release is appropriate.

Important Limitations of Use:

- Janumet XR should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.
- Janumet 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 Janumet XR.

Januvia

Monotherapy and Combination Therapy

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

Important Limitations of Use:

- Januvia should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.
- 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 is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate.

Important Limitations of Use:

- Jentadueto should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.
- Jentadueto 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 Jentadueto.

Jentadueto XR

Jentadueto 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 linagliptin and metformin is appropriate.

Important Limitations of Use:

- Jentadueto XR should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.
- Jentadueto XR 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 Jentadueto XR.

Kazano

Monotherapy and Combination Therapy

Kazano is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both alogliptin and metformin is appropriate.

Important Limitations of Use:

- Kazano should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.

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.

Important Limitations of Use:

- Kombiglyze XR should not be used for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.

Nesina

Monotherapy and Combination Therapy

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

Important Limitations of Use:

- Nesina should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.

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.

Important Limitations of Use:

- Onglyza should not be used 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 when treatment with both alogliptin and pioglitazone is appropriate.

Limitation of Use:

- Oseni should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.

Tradjenta

Monotherapy and Combination Therapy

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

Important Limitations of Use:

- Tradjenta should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.
- 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.

INITIAL STEP THERAPY

If the patient has filled a prescription for 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 system 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:

- Patient has been receiving the requested drug for at least 3 months AND demonstrated a reduction in A1c (hemoglobin A1c) since starting this therapy

OR

- Patient has the diagnosis of type 2 diabetes mellitus

AND

- Patient has experienced an inadequate treatment response, intolerance, or contraindication to metformin
- OR**
- Patient requires combination therapy AND has an A1c (hemoglobin A1c) of 7.5 percent or greater

REFERENCES

1. Janumet [package insert]. Whitehouse Station, New Jersey: Merck Sharp & Dohme Corp; January 2017.
2. Janumet XR [package insert]. Whitehouse Station, New Jersey: Merck Sharp & Dohme Corp; January 2017.
3. Januvia [package insert]. Whitehouse Station, New Jersey: Merck Sharp & Dohme Corp; January 2017.
4. Jentadueto [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; March 2017.
5. Jentadueto XR [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; March 2017.
6. Kazano [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; February 2017.
7. Kombiglyze XR [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals; February 2017.
8. Nesina [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; December 2016.

9. Onglyza [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals; February 2017.
10. Oseni [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; December 2016.
11. Tradjenta [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; March 2017.
12. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.;
http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed July 2017.
13. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically.
www.micromedexsolutions.com [available with subscription]. Accessed July 2017.
14. Standards of Medical Care in Diabetes-2017: American Diabetes Association (ADA). *Diabetes Care* January 2017;40(Supplement1).
15. Garber AJ, et al. AACE/ACE Comprehensive Diabetes Management Algorithm 2017, *Endocr Pract.* 2017; 23 (No 2).
16. Handelsman Y, Bloomgarden ZT, Grunberger G, et al. American Association of Clinical Endocrinologists and American College of Endocrinology – Clinical Practice Guidelines for developing a diabetes mellitus comprehensive care plan. *Endocr Pract.* 2015;21(Suppl 1):1-87