

### Clinical Pharmacy Program Guidelines for DPP-4 Inhibitors

Program	Prior Authorization
Medication	Janumet (sitagliptin/metformin), Janumet XR (sitagliptin/metformin extended-release), Januvia (sitagliptin), Onglyza (saxagliptin), Tradjenta (linagliptin), Kombiglyze XR (saxagliptin/metformin extended-release), alogliptin (Nesina), alogliptin/metformin (Kazano), alogliptin/pioglitazone (Oseni), Jentadueto (linagliptin/metformin), Jentadueto XR (linagliptin/metformin extended-release)
Markets in Scope	California, Colorado, Hawaii, Maryland, New Jersey, Nevada, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2009
Pharmacy and Therapeutics Approval Date	12/2020
Effective Date	2/2021

**1. Background:**

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

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

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.

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

Alogliptin/metformin (Kazano) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.

Alogliptin/pioglitazone (Oseni) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.

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

Alogliptin/metformin (Kazano), Janumet, Janumet XR, Kombiglyze XR, Jentadueto and Jentadueto XR have a black box warning for use in patients with acute or chronic metabolic acidosis. Alogliptin/pioglitazone (Oseni) has a black box warning due to heart failure. Please see full prescribing information for additional details.

## 2. Coverage Criteria:

### A. Alogliptin, alogliptin/metformin, or alogliptin/pioglitazone

1. The patient has a diagnosis of type 2 diabetes mellitus

**-AND-**

2. History of failure to metformin at a minimum dose of 1500mg daily for 90 days, or contraindication or intolerance to metformin

**Authorization will be issued for 12 months.**

### B. Januvia, Janumet, Janumet XR, Onglyza, Kombiglyze XR, Tradjenta, Jentadueto, or Jentadueto XR

1. The patient has a diagnosis of type 2 diabetes mellitus

**-AND-**

2. History of failure to metformin at a minimum dose of 1500mg daily for 90 days, or contraindication or intolerance to metformin

**-AND-**

3. History of failure for 90 days or intolerance, or contraindication to one of the following:

- Alogliptin
- Alogliptin/metformin
- Alogliptin/pioglitazone

**Authorization will be issued for 12 months.**

## 3. Additional Clinical Rules

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

#### 4. References:

1. Januvia [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; August 2019.
2. Janumet [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; August 2019.
3. Onglyza [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2019.
4. Kombiglyze XR [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2019.
5. Tradjenta [package insert]. Ridgefield, CT: Boehringer Ingelheim; April 2020.
6. American Diabetes Association. Standards of Medical Care in Diabetes—2020. Diabetes Care Jan 2020, 43 (Supplement 1) S1-S2.
7. Janumet XR [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; August 2019.
8. Inzucchi SE, Bergenstal RM, Buse JB, et al. Management of hyperglycemia in type 2 diabetes: a patient centered approach. Diabetes Care. 2012, 19 April 2012 [Epub ahead of print]
9. Nesina [package insert]. Deerfield, IL: Takeda Pharmaceuticals, Inc.; June 2019.
10. Kazano [package insert]. Deerfield, IL: Takeda Pharmaceuticals, Inc.; June 2019.
11. Oseni [package insert]. Deerfield, IL: Takeda Pharmaceuticals, Inc.; November 2019.
12. American Diabetes Association. Standards of medical care in diabetes. Diabetes Care. 2013; 36 (suppl 1): S11-S66.
13. Jentaduetto [package insert]. Ridgefield, CT: Boehringer Ingelheim; March 2020.
14. ACE Comprehensive Diabetes Management Algorithm, Endocr Pract. 2013;19 (No. 2)
15. Jentaduetto XR [package insert]. Ridgefield, CT: Boehringer Ingelheim; April 2020.
16. Garber A, Abrahamson M, Barzilay J, et al. Consensus statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the Comprehensive Type 2 Diabetes Management Algorithm. Endocr Prac. 2017;23(2)207-238.
17. Davies MJ, et al.; Management of hyperglycaemia in type 2 diabetes, 2018. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD), Diabetologia 2018.

Program	Prior Authorization –DPP 4 Inhibitors
<b>Change Control</b>	
Date	Change
9/2009	Criteria were taken from previously approved Unison policy (RX12 TZDs/DPP-4). Policy was reformatted.

12/2010	Annual Review
9/2011	Annual Review. Added Onglyza, Kombiglyze XR, and Tradjenta to non-preferred product list.
6/2012	Added Janumet XR to policy as a preferred product subject to the step therapy guideline.
6/2013	Added Onglyza and Kombiglyze to preferred drug list and step therapy criteria. Added alogliptin products to non-preferred drug list.
9/2014	Changed preferred drug list. Step therapy now applies to Onglyza, Kombiglyze XR, Tradjenta, and Jentadueto. Step therapy no longer applies to Januvia, Janumet, and Janumet XR due to PDL deletion.
12/2014	Criteria format updated to align with SGLT-2 and GLP-1. Added new non-preferred section for Januvia, Janumet, Janumet XR, Nesina, Kazano, and Oseni requiring type 2 diabetes diagnosis, trial of metformin, and prior use of preferred DPP-4 agents.
10/2016	Added Jentadueto XR to policy. Added authorization durations. Added trial of an alogliptin-containing product to Section B. Updated references and policy template.
11/2016	Updated medications in Section A and B based on PDL status. Removed double-step in Section B since alogliptin-containing products are the only preferred DPP-4 inhibitors.
9/2017	Annual review. Updated references.
9/2018	Annual review. Updated references.
9/2019	Annual review. Updated references. Added language clarifying treatment failure length for preferred products is 90 days.
12/2019	Updated background. No changes to clinical intent.
12/2020	Annual review. Updated background and references.