

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2245-13
Program	Prior Authorization/Medical Necessity – Custom Oxford SoNY and SoCT - Diabetes Medications - DPP4 Inhibitors
Medication	Januvia® (sitagliptin)*, Janumet® (sitagliptin/metformin immediate-release)*, Janumet® XR (sitagliptin/metformin extended-release)*, Sitagliptin (Zituvio™ authorized generic)*, Sitagliptin/Metformin (Zituvimet authorized generic)*, Sitagliptin/Metformin extended-release (Zituvimet XR authorized generic)*, Zituvio (sitagliptin)*, Zituvimet*, Zituvimet XR (sitagliptin/metformin extended-release)*
P&T Approval Date	10/2016, 10/2017, 10/2018, 10/2019, 4/2020, 5/2020, 8/2020, 7/2021, 9/2022, 4/2024, 7/2024, 11/2024, 7/2025
Effective Date	Oxford: 10/1/2025

1. Background:

Januvia (sitagliptin)* and Zituvio (sitagliptin)* are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Janumet (sitagliptin/metformin)*, Janumet XR (sitagliptin/metformin extended-release)*, Sitagliptin/Metformin (Zituvimet authorized generic)*, Sitagliptin/Metformin extended-release (Zituvimet XR authorized generic)* Zituvimet, and Zituvimet XR* are 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/metformin extended-release is appropriate.

2. Coverage Criteria^a:

A. Januvia*, Sitagliptin (Zituvio authorized generic)* or Zituvio* will be approved based on the following criterion:

1. History of a three-month trial resulting in a therapeutic failure, contraindication (e.g., risk factors for heart failure), or intolerance to **both** of the following (list reason for therapeutic failure, contraindication, or intolerance)^b:

- a. Tradjenta (linagliptin)

-AND-

- b. **One** of the following:

- (1) Alogliptin (Nesina* authorized generic)
 - (2) saxagliptin (generic Onglyza)*

Authorization will be issued for 12 months

B. Janumet*, Janumet XR*, Sitagliptin/Metformin* (Zituvimet authorized generic), Sitagliptin/Metformin extended-release* (Zituvimet XR authorized generic), Zituvimet* or Zituvimet XR* will be approved based on the following criterion:

<p>1. History of a three-month trial resulting in a therapeutic failure, contraindication (e.g., risk factors for heart failure), or intolerance to all of the following (list reason for therapeutic failure, contraindication, or intolerance)^b:</p> <p>a. Jentaducto (linagliptin/metformin immediate-release)/Jentaducto XR (linagliptin/metformin extended-release)</p> <p style="text-align: center;">-AND-</p> <p>b. One of the following:</p> <p style="padding-left: 40px;">(1) Alogliptin/Metformin immediate-release (Kazano* authorized generic)</p> <p style="padding-left: 40px;">(2) saxagliptin/metformin extended-release (generic Kombiglyze XR)*</p> <p>Authorization will be issued for 12 months</p> <p>^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.</p> <p>^b For Connecticut business only a 30 day trial will be required.</p>
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***Januvia, Janumet, Janumet XR, multi-source brand Onglyza, multi-source brand Kombiglyze XR, Kazano, Nesina, Zituvio, (including the authorized generic), Zituvimet (including the authorized generic) and Zituvimet XR (including the authorized generic) are typically excluded from coverage**

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]. Rahway, NJ: Merck & CO. Inc.; July 2023.
2. Janumet [package insert]. Rahway, NJ: Merck & CO. Inc.; July 2022.
3. Janumet XR [package insert]. Rahway, NJ: Merck & Co., Inc.; July 2022.
4. Zituvimet/Zituvimet XR [package insert]. Pennington, NJ: Zydus Pharmaceuticals (USA) Inc.; July 2024.
5. Zituvio [package insert]. Pennington, NJ: Zydus Pharmaceuticals Inc; January 2025.
6. American Diabetes Association. Standard of Medical Care in Diabetes- 2025. Diabetes Care 2025;48 (Supplement 1)

Program	Prior Authorization/Medical Necessity – Diabetes Medication- DPP4 Inhibitors
Change Control	
10/2016	New - Replacing Diabetes Medication Notification program P1025 originally P&T approved 11/2012.
10/2017	Annual review. Updated references. State mandate reference language updated.

10/2018	Annual review. Updated references. Added Jentadueto XR as a Step 1 option.
10/2019	Annual review. Added information on automated approval language.
4/2020	Removed the automated approval language.
5/2020	Added Januvia, Janumet and Janumet are typically excluded from coverage.
8/2020	Added requirement for submission of medical records.
7/2021	Annual review. Updated references. Program type changed from Prior Authorization/Notification (P 1198-7) to Prior Authorization/Medical Necessity (P 2245-8).
9/2022	Annual review. Updated references.
4/2024	Updated products typically excluded from coverage. Updated references.
7/2024	Added Zituvio and updated Nesina and Kazano to the authorized generic products. Updated references.
11/2024	Added Sitagliptin (Zituvio authorized generic), Sitagliptin/Metformin (by Zydus) Zituvimet and Zituvimet XR. Updated references.
7/2025	Added Zituvimet XR authorized generic. Updated to generic Kombiglyze and Onglyza. Updated references.