

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2024 P 2245-12 |
| 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), 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 |
| Effective Date | Oxford: 2/1/2025 |

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, 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:

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| <p>A. Januvia*, Sitagliptin (Zituvio authorized generic)* or Zituvio* will be approved based on the following criterion:</p> <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> a. Tradjenta (linagliptin) <p style="text-align: center;">-AND-</p> <ol style="list-style-type: none"> b. One of the following: <ol style="list-style-type: none"> (1) Alogliptin (Nesina* authorized generic) (2) Onglyza* (saxagliptin) <p style="text-align: center;">Authorization will be issued for 12 months</p> <p>B. Janumet*, Janumet XR*, Sitagliptin/Metformin* (Zituvimet authorized generic), Zituvimet* or Zituvimet XR* will be approved based on the following criterion:</p> <ol style="list-style-type: none"> 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: |
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| <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>(1) Kazano Alogliptin/Metformin immediate-release (Kazano* authorized generic)</p> <p>(2) Kombiglyze XR* (saxagliptin/metformin extended-release)</p> <p style="text-align: center;">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 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; July 2024.
6. American Diabetes Association. Standard of Medical Care in Diabetes- 2024. Diabetes Care 2024;47 (Supplement 1)

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| 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 Jentaducto XR as a Step 1 option. |

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| 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. |