UnitedHealthcare®

D to UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3084-12
Program	Step Therapy – 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, 1/2018, 10/2019, 4/2020, 5/2020, 5/2021, 2/2022, 1/2023, 1/2024, 7/2024, 11/2024
Effective Date	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,b]:

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)[c]:

   a. Tradjenta (linagliptin)

   -AND-

   b. **One** of the following:

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

Authorization will be issued for 12 months

B. Janumet*,Janumet XR*, Sitagliptin/Metformin* (Zituvimet authorized generic), Zituvimet* or Zituvimet XR* 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 **all** of the following (list reason for therapeutic failure, contraindication, or intolerance)[c]:

a. Jentadueto (linagliptin/metformin immediate-release)/Jentadueto XR (linagliptin/metformin extended-release)

-AND-

b. **One** of the following:

(1) Alogliptin/Metformin immediate-release (Kazano* authorized generic)
(2) Kombiglyze XR* (saxagliptin/metformin extended-release)

Authorization will be issued for 12 months

[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.

[b] In Florida, Maine, and Tennessee only, diabetes medications may be approved based on both of the following: 1) Provider attests use of this product is medically necessary; and- 2) If applicable, clinical characteristics exist that preclude the use of the covered preferred alternative(s) and use of the covered preferred alternative(s) could result in worsening of patient's condition or inadequate treatment (document alternatives and clinical information related to worsening/inadequate treatment).

[c] For Connecticut, Kentucky and Mississippi business, only a 30-day trial will be required

***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)

Program	Step Therapy – Diabetes Medication
Change Control	
10/2016	New – Replacing Diabetes Medication Step Therapy program P3018 originally P&T approved 12/2013.
10/2017	Annual review. Updated references.

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. Updated references.
5/2021	Annual review. Updated references.
2/2022	Added Florida, Maine, and Tennessee mandate language. Updated Connecticut/Kentucky mandate language. Updated references.
1/2023	Annual review. Updated the mandate language to include Mississippi. Updated references.
1/2024	Annual review. Updated mandate language for Connecticut. 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.