

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2022 P 3084-8
Program	Step Therapy – Diabetes Medications- DPP4 Inhibitors
Medication	Januvia (sitagliptin)*, Janumet (sitagliptin/metformin immediate-release)*, Janumet 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
Effective Date	5/1/2022; Oxford only: 5/1/2022

**1. Background:**

Januvia (sitagliptin)\* is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Janumet (sitagliptin/metformin)\* and Janumet XR (sitagliptin/metformin extended-release)\* 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<sup>a,b</sup>:**

**A. Januvia\*** 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)<sup>c</sup>:

- a. Tradjenta (linagliptin)

-AND-

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

- (1) Nesina (alogliptin)
- (2) Onglyza (saxagliptin)

**Authorization will be issued for 12 months**

**B. Janumet\* and Janumet 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)<sup>c</sup>:

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

-AND-

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

- (1) Kazano (alogliptin/metformin immediate-release)
- (2) Kombiglyze XR (saxagliptin/metformin extended-release)

**Authorization will be issued for 12 months**

- <sup>a</sup> 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.
- <sup>b</sup> 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).
- <sup>c</sup> For Connecticut business, only a 60-day trial will be required. For Kentucky business, only a 30-day trial will be required

**\*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]. Whitehouse Station, NJ: Merck & CO. Inc.; December 2021.
2. Janumet [package insert]. Whitehouse Station, NJ: Merck & CO. Inc.; December 2021.
3. Janumet XR [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; December 2021.
4. American Diabetes Association. Standard of Medical Care in Diabetes- 2021. Diabetes Care 2022;45 (Supplement 1)

Program	Step Therapy – Diabetes Medication
<b>Change Control</b>	
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 Jentaducto 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.