UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2022 P 2245-9
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)*
P&T Approval Date	10/2016, 10/2017, 10/2018, 10/2019, 4/2020, 5/2020, 8/2020, 7/2021, 9/2022
Effective Date	Oxford: 12/1/2022

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[a]:

A. Januvia* will be approved based on the following criterion:

1. Submission of medical records documenting a history of a three month trial[b] resulting in a therapeutic failure, contraindication (e.g. risk factors for heart failure), or intolerance to **both** of the following (Document date and duration of trial):

   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. Submission of medical records documenting a history of a three month trial[b] resulting in a therapeutic failure, contraindication (e.g. risk factors for heart failure), or intolerance to **all** of the following (Document date and duration of trial):

   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

[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] For Connecticut 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 2021;44 (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.