



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

| | |
|-------------------|--|
| Program Number | 2020 P 3084-6 |
| 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 |
| Effective Date | 7/1/2020; Oxford only: 7/1/2020 |

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. 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) 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)^b:

- 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 and 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.; August 2019.
2. Janumet [package insert]. Whitehouse Station, NJ: Merck & CO. Inc.; August 2019.
3. Janumet XR [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; August 2019.
4. Jentadueto/Jentadueto XR [package insert]. Ridgefield, CT: Boehringer-Ingelheim Pharmaceuticals, Inc.; July 2019.
5. Kazano [package insert]. Deerfield, IL: Takeda Pharmaceutical America, Inc.; June 2019.
6. Kombiglyze XR [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals; June 2019.
7. Nesina [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; June 2019.
8. Onglyza [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals; June 2019
9. Tradjenta [package insert]. Ridgefield, CT: Boehringer-Ingelheim Pharmaceuticals, Inc.; July 2019.
10. American Diabetes Association. Standard of Medical Care in Diabetes- 2020. Diabetes Care 2020;43 (Supplement 1)
11. American Diabetes Association; Cardiovascular Disease and Risk Management: Standards of Medical Care in Diabetes. Diabetes Care 2020 Jan; 41(Supplement 1): S86-S104.

| 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. |