



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2018 P 3084-3
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, 10/2018
Effective Date	2/1/2019; Oxford only: 2/1/2019

**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</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>b</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>b</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> For Connecticut and Kentucky business, only a 30 day trial will be required.

**3. Additional Clinical Rules:**

- Supply limits may be in place.

**4. References:**

1. Januvia prescribing information. Merck & CO. Inc. Whitehouse Station, New Jersey. February 2018.
2. Janumet prescribing information. Merck & CO. Inc. Whitehouse Station, New Jersey. February 2018.
3. Janumet XR prescribing information. Merck & Co., Inc., Whitehouse Station, New Jersey. February 2018.
4. Jentadueto/Jentadueto XR prescribing information. Boehringer-Ingelheim Pharmaceuticals, Inc. Ridgefield, Connecticut. August 2017.
5. Kazano prescribing information. Takeda Pharmaceutical America, Inc. Deerfield, IL. February 2017.
6. Kombiglyze XR prescribing information. AstraZeneca Pharmaceuticals. Wilmington, DE. February 2017.
7. Nesina prescribing information. Takeda Pharmaceuticals America, Inc. Deerfield, IL. December 2016.
8. Onglyza prescribing information. AstraZeneca Pharmaceuticals. Wilmington, DE. April 2018.
9. Tradjenta prescribing information. Boehringer-Ingelheim Pharmaceuticals, Inc. Ridgefield, Connecticut. August 2017.
10. American Diabetes Association; Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes 2018, Diabetes Care 2018 Jan;41 (Supplement 1):S73-S85.
11. American Diabetes Association; Cardiovascular Disease and Risk Management: Standards of Medical Care in Diabetes. Diabetes Care 2018 Jan; 41(Supplement 1): S86-S104.

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.