

Cigna National Preferred Formulary Coverage Policy



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Coverage Policy Number NPF089

Preferred Step Therapy Diabetes – Dipeptidyl Peptidase-4 Inhibitors

Table of Contents

NPF Coverage Policy	1
Background.....	2
References	2
Last Revision Details	3

Related Coverage Resources

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

NPF Coverage Policy

Drugs Affected

- Janumet® (sitagliptin/metformin tablets)
- Janumet® XR (sitagliptin/metformin extended-release tablets)
- Januvia® (sitagliptin tablets)
- Jentadueto® (linagliptin/metformin tablets)
- Jentadueto® XR (linagliptin/metformin extended-release tablets)
- Kazano™ (alogliptin/metformin tablets generics)
- Kombiglyze™ XR (saxagliptin/metformin extended-release tablets)
- Nesina® (alogliptin tablets, generics)
- Onglyza® (saxagliptin tablets)
- Tradjenta® (linagliptin tablets)

A step therapy program has been developed to encourage the use of a Step 1 product prior to the use of a Step 2 product. If the step therapy rule is not met for the Step 2 agent at the point of service, then coverage will be determined by step therapy criteria below. All approvals are provided for 1 year in duration.

Step 1: Januvia, Janumet, Janumet XR

Step 2: Nesina, alogliptin, Kazano, alogliptin/metformin, Onglyza, Kombiglyze XR, Jentadueto, Jentadueto XR, Tradjenta

Cigna covers Step 2 agents as medically necessary when the following criteria are met:

1. If the individual has tried a Step 1 product, approve a Step 2 product.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

The dipeptidyl peptidase-4 (DPP-4) inhibitors Januvia, Nesina, Onglyza, Tradjenta as well as their various combinations Janumet, Janumet XR, Jentadueto, Jentadueto XR, Kazano, and Kombiglyze XR are indicated in adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.¹⁻¹⁰

Guidelines

The DPP-4 inhibitors are regarded as having intermediate efficacy for reduction in glycosylated hemoglobin, being weight neutral, and having a low risk of hypoglycemia.^{11,12} Guidelines do not express preference for one DPP-4 inhibitor over the others in individuals with type 2 diabetes. The American Diabetes Association Standards of Care (2020) note cardiovascular (CV) outcomes data for the DPP-4 inhibitors have shown no significant difference in rates of major CV events between treatment and placebo groups in any of these trials.¹² The Standards do acknowledge potential heart failure (HF) risk associated with Nesina and Onglyza. In SAVOR-TIMI 53, significantly more HF hospitalizations were observed with Onglyza vs. placebo; a non-significant trend toward increased HF hospitalization occurred with Nesina vs. placebo in EXAMINE.

In most cases, metformin is regarded as first-line therapy in individuals with type 2 diabetes.^{11,12} When glycemic control is not achieved with metformin other agents may be added. The sequencing of add-on therapies varies between the algorithms and is based on individual characteristics, including glycemic control and comorbid medical conditions. The DPP-4 inhibitors are generally regarded as add-on therapy when glycemic control is not achieved with metformin. If metformin is not a first-line option, DPP-4 inhibitors may be considered. There is no preference for one DPP-4 inhibitor over the others.

References

1. Janumet® tablets [prescribing information]. Whitehouse Station, NJ: Merck; August 2019.
2. Janumet® XR tablets [prescribing information]. Whitehouse Station, NJ: Merck; August 2019.
3. Januvia® tablets [prescribing information]. Whitehouse Station, NJ: Merck; August 2019.
4. Jentadueto® tablets [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; March 2020.
5. Jentadueto® XR tablets [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; March 2020.
6. Kazano™ tablets [prescribing information]. Deerfield, IL: Takeda; June 2019.
7. Kombiglyze™ XR tablets [prescribing information]. Wilmington, DE: AstraZeneca; June 2019.
8. Nesina® tablets [prescribing information]. Deerfield, IL: Takeda; June 2019.
9. Onglyza® tablets [prescribing information]. Wilmington, DE: AstraZeneca; June 2019.
10. Tradjenta® tablets [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; March 2020.

11. Garber AJ, Handelsman Y, Grunberger G, et al. Consensus statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the comprehensive type 2 diabetes management algorithm – 2020 executive summary. *Endocr Pract.* 2020;26(1):107-139.
12. American Diabetes Association. Standards of medical care in diabetes – 2020. *Diabetes Care.* 2020;43(Suppl 1):S1-S212. Available at: https://care.diabetesjournals.org/content/43/Supplement_1. Accessed on October 5, 2020.

Last Revision Details

Annual Revision	Tradjenta, Jentadueto, and Jentadueto XR moved from Step 1 to Step 2.	10/14/2020; Effective 01/01/2021
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