

CARE VALUE POLICY

- POLICY:** Diabetes – Dipeptidyl Peptidase-4 Inhibitors Care Value Policy
- Janumet[®] (sitagliptin/metformin tablets – Merck)
 - Janumet[®] XR (sitagliptin/metformin extended-release tablets – Merck)
 - Januvia[®] (sitagliptin tablets – Merck)
 - Jentadueto[®] (linagliptin/metformin tablets – Boehringer Ingelheim/Eli Lilly)
 - Jentadueto[®] XR (linagliptin/metformin extended-release tablets – Boehringer Ingelheim/Eli Lilly)
 - Kazano[™] (alogliptin/metformin tablets – Takeda, generics)
 - Kombiglyze[™] XR (saxagliptin/metformin extended-release tablets – Bristol-Meyers Squibb)
 - Nesina[®] (alogliptin tablets – Takeda, generics)
 - Onglyza[®] (saxagliptin tablets – Bristol-Meyers Squibb)
 - Tradjenta[®] (linagliptin tablets – Boehringer Ingelheim/Eli Lilly)

REVIEW DATE: 10/14/2020

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 patients 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 patients 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 patient 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.

POLICY STATEMENT

This Care Value program has been developed to encourage the use of a Step 1 drug prior to the use of a Step 2 drug. If the Preferred Step Therapy rule is not met for the Step 2 drug the point of service, coverage will be determined by the Preferred Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a history of one Step 1 drug within the 130-day look-back period is excluded from Step Therapy.

Step 1: Januvia, Janumet, Janumet XR

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

CRITERIA

1. If the patient has tried a Step 1 drug, approve a Step 2 drug.
2. No other exceptions are recommended.

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, Grumberg 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.