PREFERRED STEP THERAPY POLICY

POLICY:

Diabetes – Dipeptidyl Peptidase-4 Inhibitors Preferred Step Therapy 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, generic)
- Kombiglyze[™] XR (saxagliptin/metformin extended-release tablets Bristol-Meyers Squibb)
- Nesina® (alogliptin tablets Takeda, generic)
- Onglyza[®] (saxagliptin tablets Bristol-Meyers Squibb)
- Tradjenta® (linagliptin tablets Boehringer Ingelheim/Eli Lilly)

REVIEW DATE: 11/09/2022

OVERVIEW

The dipeptidyl peptidase-4 (DPP-4) inhibitors alogliptin, Januvia, Onglyza, Tradjenta as well as their various combinations alogliptin/metformin, Janumet, Janumet XR, Jentadueto, Jentadueto XR, and Kombiglyze XR are indicated as adjuncts 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 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 program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Preferred Step Therapy rule is not met for the Step 2 Product at the point of service, coverage will be determined by the Preferred Step Therapy criteria below. All approvals are provided for 1 year in duration.

<u>Automation</u>: A patient with a of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

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- **Step 1:** Januvia, Janumet, Janumet XR
- **Step 2:** alogliptin (Nesina, generic), alogliptin/metformin (Kazano, generic), Jentadueto, Jentadueto XR, Kombiglyze XR, Onglyza, Tradjenta

CRITERIA

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

REFERENCES

- 1. Janumet® tablets [prescribing information]. Whitehouse Station, NJ: Merck; June 2022.
- 2. Janumet® XR tablets [prescribing information]. Whitehouse Station, NJ: Merck; June 2022.
- 3. Januvia® tablets [prescribing information]. Whitehouse Station, NJ: Merck; June 2022.
- 4. Jentadueto® tablets [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; April 2022.
- 5. Jentadueto® XR tablets [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; October 2021.
- Kazano[™] tablets [prescribing information]. Deerfield, IL: Takeda; March 2022.
- 7. Kombiglyze[™] XR tablets [prescribing information]. Wilmington, DE: AstraZeneca; June 2019.
- 8. Nesina® tablets [prescribing information]. Deerfield, IL: Takeda; March 2022.
- 9. Onglyza® tablets [prescribing information]. Wilmington, DE: AstraZeneca; June 2019.
- 10. Tradjenta® tablets [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; April 2022.
- 11. Blonde L, Umpierrez GE, Reddy SS, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan-2022 Update. *Endocr Pract.* 2022 Oct;28(10):923-1049.
- 12. American Diabetes Association. Standards of medical care in diabetes 2022. Diabetes Care. 2022;45(Suppl 1):S1-S258.