MEDICAL MUTUAL®

Drug Policy

Policy:	**Dipeptidyl Peptidase-4 (DPP-4) Inhibitors** **Preferred Step Therapy Policy**	**Annual Review Date:** **01/19/2023** **Last Revised Date:** **01/19/2023**

OVERVIEW

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

The DPP-4 inhibitors have demonstrated similar reductions in glycemic parameters (glycosylated hemoglobin [HbA_{1C}], fasting plasma glucose [FPG] and post-prandial glucose [PPG]) in clinical trials as monotherapy as well as in addition to metformin, sulfonylureas, and thiazolidinediones (no head-to-head trials are available between the DPP-4 inhibitors). In general, it is estimated that the DPP-4 inhibitors will reduce HbA_{1C} by 0.5% to 0.9% as monotherapy. The DPP-4 inhibitors are also regarded as being weight neutral and having a low risk of hypoglycemia. Guidelines from the American Association of Clinical Endocrinologists (AACE) and the American Diabetes Association (ADA) do not express preference for one DPP-4 inhibitor over the others in patients with type 2 diabetes.

POLICY STATEMENT

A step therapy program has been developed to encourage the use of Januvia, Janumet, or Janumet XR, (Step 1) prior to the use of Onglyza, Kombiglyze XR, Nesina, Kazano, Oseni, Tradjenta, Jentadueto, Jentadueto XR, alogliptin or alogliptin/metformin. (Step 2). 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.

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

Preferred Medications

- Janumet® (sitagliptin/metformin tablets)
- Janumet® XR (sitagliptin/metformin extended-release tablets)
- Januvia® (sitagliptin tablets)

Non-Preferred Medications

- Kazano™ (alogliptin/metformin tablets)
- Nesina® (alogliptin tablets)

- Alogliptin and alogliptin/metformin tablets (branded generic)
- Onglyza® (saxagliptin tablets)
- Kombiglyze™ XR (saxagliptin/metformin extended-release tablets)
- Oseni (alogliptin/pioglitazone tablets)
- Tradjenta® (linagliptin tablets)
- Jentadueto® (linagliptin/metformin tablets)
- Jentadueto® XR (linagliptin/metformin extended-release tablets)

PREFERRED STEP THERAPY CRITERIA

1. If the patient has tried a preferred medication, then authorization for a non-preferred medication may be given.

Step Therapy Exception Criteria

In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**

B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**

C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:

    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

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Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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- Kombiglyze™ XR tablets [prescribing information]. Princeton, NJ. Bristol-Meyers Squibb Company; June 2014.
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- Oseni [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; December 2017.
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