Pharmacy Medical Necessity Guidelines: Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Effective: January 1, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

The dipeptidyl peptidase-4 (DPP-4) inhibitors are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus as monotherapy or combination therapy.

Per American Diabetes Association (ADA) guidelines, metformin and lifestyle changes are considered first line in the treatment of type 2 diabetes. DPP-4 inhibitors are considered add-on treatment options if glycemic targets are not achieved after approximately three months of metformin monotherapy. Sulfonylureas, thiazolidinediones, sodium-glucose co-transporter 2 (SGLT2) inhibitors, GLP-1 agonists, and basal insulin are also considered add-on treatments to metformin. The choice of add-on treatment is patient-specific.

COVERAGE GUIDELINES

The plan may authorize coverage of a dipeptidyl peptidase-4 inhibitor for Members when **all** of the following criteria for a particular regimen are met and limitations do not apply:

For alogliptin, alogliptin-metformin, alogliptin-pioglitazone

1. Member has had an inadequate response, intolerance, or contraindication to one of the following:
   a) metformin

   OR

   b) metformin-sulfonylurea combination product

   OR

   c) metformin-thiazolidinedione combination product

LIMITATIONS

1. The coverage of alogliptin and alogliptin-pioglitazone is limited to one tablet per day.
2. The coverage of alogliptin-metformin is limited to two tablets per day.

CODES

None

REFERENCES

1. Oseni (alogliptin/pioglitazone) [prescribing information]. Takeda Pharmaceuticals America, Inc.; Deerfield, IL; June 2019.
2. Nesina (alogliptin) [prescribing information]. Takeda Pharmaceuticals America, Inc.: Deerfield, IL; June 2019.
3. Kazano (alogliptin/metformin) [prescribing information]. Takeda Pharmaceuticals America, Inc.: Deerfield, IL; June 2019.

4. 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.
5. American Diabetes Association. Standards of medical care in diabetes – 2020. *Diabetes Care*. 2020;43(Suppl. 1):S1-S212.

APPROVAL HISTORY

June 12, 2014: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. May 12, 2015: Removed Kombiglyze from the criteria since it is a non-covered medication; consolidated criteria for Kazano, Onglyza, Oseni and Nesina for consistency; approval duration modified to one year; renewal criteria added.
2. September 16, 2015: Approval duration approved for life of plan
3. January 1, 2016: Administrative change to rebranded template.
4. August 9, 2016: Removed alogliptin, alogliptin/metformin, alogliptin/pioglitazone, and Onglyza from the criteria as they are non-covered medications.
5. September 13, 2016: Moved alogliptin, alogliptin-metformin, alogliptin-pioglitazone, and Onglyza to the policy with prior authorization criteria. Added Jentadueto XR to the criteria. Updated criteria for Janumet, Janumet XR, Januvia, Jentadueto, and Tradjenta to require previous treatment with an alogliptin-containing product.
6. October 18, 2016: Moved Januvia, Janumet, Janumet XR, Jentadueto, Jentadueto XR, Onglyza and Tradjenta to Not Covered.
7. May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template
8. September 12, 2017: No changes.
9. October 16, 2018: Administrative changes made to template.
10. April 9, 2019: No changes.
11. March 10, 2020: No changes.
12. November 24, 2020: Effective 1/1/2021, MNG is retired.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.