MEDICAL MUTUAL®

Drug Policy

Policy:	Sodium Glucose Co-Transporter-2 (SGLT2)/Dipeptidyl Peptidase-4 (DPP-4) Inhibitor Preferred Step Therapy Policy	Annual Review Date: 02/15/2024 Last Revised Date: 02/15/2024

OVERVIEW

Glyxambi, Qtern, Steglujan, and Trijardy XR are sodium glucose co-transporter-2 inhibitor (SGLT-2) and dipeptidyl peptidase-4 (DPP-4) inhibitor combination products indicated as an adjunct to diet and exercise to improve glycemic control in adults with **type 2 diabetes mellitus**; Trijardy XR also contains metformin.[1-4] Various single-entity SGLT-2 inhibitors and DPP-4 inhibitors are available. In addition to their indications for type 2 diabetes, Jardiance® (empagliflozin tablets), Invokana® (canagliflozin tablets), and Farxiga® (dapagliflozin tablets) possess indications related to cardiovascular, renal, and/or heart failure benefits. Efficacy of the SGLT-2 inhibitor combination products has not been established in these settings. Refer to Table 1 for a summary of the available products containing SGLT-2 and/or DPP-4 inhibitors.

POLICY STATEMENT

A step therapy program has been developed to encourage the use of a preferred (metformin-containing) product prior to the use of a non- preferred product. If the step therapy rule is not met for a non- preferred agent at the point of service, coverage will be determined by the step therapy criteria below. All approvals are provided for 12 months in duration.

Automation:

1. Glyxambi or Trijardy XR automation:
    a. A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy. Additionally, a patient with a history of one DPP-4 inhibitor (e.g., Januvia, Nesina, alogliptin, Onglyza, Tradjenta), Oseni, alogliptin/pioglitazone, or one SGLT-2 inhibitor (e.g., Farxiga, Invokana, Jardiance, Steglatro) within the 130-day look-back period is excluded from Step Therapy.

Preferred (step 1): generic metformin, generic metformin extended-release (generic to Glucophage XR only)

Non-Preferred (step 2): Glyxambi, Trijardy XR

CRITERIA

1. If the patient has tried one step 1 product, authorization for a step 2 product may be given.

Note: A trial of one of the following metformin-containing products also satisfies the requirement: Glucophage, Glucophage XR, Glumetza, Fortamet, Riomet, metformin oral solution, Riomet ER, metformin extended-release (generics to Fortamet and Glumetza), metformin/glyburide, metformin/glipizide, Actoplus Met, pioglitazone/metformin, Actoplus Met XR, Janumet, Janumet XR, repaglinide/metformin, Kombiglyze XR, Jentadueto, Jentadueto XR, Kazano, aloglitpin/metformin, Synjardy, Synjardy XR, Xigduo XR, Invokamet, Invokamet XR, Segluromet.

2. If the patient has tried a DPP-4 inhibitor (e.g., Januvia, Nesina, alogliptin, Onglyza, Tradjenta), DPP-4 inhibitor-containing product (e.g., Oseni, alogliptin/pioglitazone), or an SGLT-2 inhibitor (e.g., Farxiga, Invokana, Jardiance, Steglatro), other than Glyxambi, Qtern, Steglujan, or Trijardy XR, approve a Step 2 Product.

3. If the patient has a contraindication to metformin, according to the prescriber, approve Glyxambi.
(Note: Examples of contraindications to metformin include acute or chronic metabolic acidosis, including diabetic ketoacidosis).

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days (1 year)
B) *Extended Approval:* 365 days (1 year)

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).

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

1. Glyxambi® tablets [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; October 2022.
2. Qtern® tablets [prescribing information]. Wilmington, DE: AstraZeneca; October 2022.
3. Steglujan® tablets [prescribing information]. Whitehouse Station, NJ: Merck; October 2022.
4. Trijardy® XR tablets [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; October 2022.
5. American Diabetes Association. Standards of medical care in diabetes – 2023. *Diabetes Care*. 2023;46(Suppl 1):S1-S291.
6. Davies MJ, Aroda VR, Collins BS, et al. Management of hyperglycemia in type 2 diabetes, 2022. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care.* 2022;45(11):2753-2786.
7. Metformin tablets [prescribing information]. Raleigh, NC: Indicus; June 2020.
8. 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;18:923-1049.