MEDICAL MUTUAL®

Drug Policy

Policy:	Sodium Glucose Co-Transporter-2 (SGLT-2) Inhibitors Preferred Step Therapy Policy	Annual Review Date: 12/19/2024 Last Revised Date: 12/19/2024

OVERVIEW

Brenzavvy, dapagliflozin, Invokana, Jardiance, and Steglatro are sodium glucose co-transporter-2 (SGLT-2) inhibitors indicated as an adjunct to diet and exercise to improve glycemic control in adults with **type 2 diabetes**. Dapagliflozin and Jardiance are also indicated in pediatric patients ≥ 10 years of age with type 2 diabetes as an adjunct to diet and exercise to improve glycemic control.

POLICY STATEMENT

A step therapy program has been developed to encourage the use of a Step 1 product prior to the use of a Step 2 product or the use of any combination of two Step 1 or Step 2 products before the use of a step 3 product. If the step therapy rule is not met for a Step 2 or Step 3 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: The following automation is applied in this policy:

- ICD-10 codes for Heart Failure (ICD-10: **I50.2* and I50.4***) will be used for automation to allow approval for Farxiga or Jardiance.
- ICD-10 codes for Chronic Kidney Disease (ICD-10: **N18.*)** will be used for automation to allow approval of Farxiga or Jardiance.
- **Requests for a Step 2 Product:** A patient with a history of one of the following within the 130-day look-back period is excluded from Step Therapy:
  - One Step 1 Product; OR
  - One of the following metformin-containing products: Glumetza ER, Riomet, metformin oral solution, Riomet ER, metformin extended-release (generics to Fortamet ER and Glumetza ER), glyburide/metformin, glipizide/metformin, Actoplus Met, pioglitazone/metformin, Kazano, alogliptin/metformin, Jentadueto, Jentadueto XR, Kombiglyze XR, saxagliptin/metformin extended-release, Janumet, sitagliptin/metformin (authorized generic), Janumet XR; OR
  - One Step 2 Product AND one step 1 product within a 720-day look-back period; OR
  - One Step 3 Product AND one step 1 product within a 720-day look-back period.
- **Requests for a Step 3 Product:**
  - A patient with a history of one Step 2 Product within the 130-day look-back period AND one step 1 product within a 720-day look-back period is excluded from Step Therapy; OR
  - A patient with a history of one Step 3 Product within the 130-day look-back period AND one step 1 product AND one step 2 product within a 720-day look-back period is excluded from Step Therapy.

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

Step 2: Brenzavvy, Farxiga, Jardiance, Synjardy, Synjardy XR, Xigduo XR

Step 3: Segluromet, Steglatro

CRITERIA

Step 2 Products

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
   Note: A trial of one of the following metformin-containing products also satisfies the requirement: Fortamet ER (obsolete), Glucophage (obsolete), Glucophage XR (obsolete), Glumetza ER, Riomet, metformin oral solution, Riomet ER, metformin extended-release (generics to Fortamet ER and Glumetza ER), glyburide/metformin, glipizide/metformin, Actoplus Met, pioglitazone/metformin, Actoplus Met XR (obsolete), repaglinide/metformin (obsolete), Kazano, alogliptin/metformin, Jentadueto, Jentadueto XR, Kombiglyze XR, saxagliptin/metformin extended-release, Janumet, sitagliptin/metformin (authorized generic), Janumet XR.

2. If the patient has tried one Step 2 Product, approve the requested Step 2 Product.

3. If the patient has tried one Step 3 Product, approve the requested Step 2 Product.

4. If the patient will be initiating dual therapy with metformin AND Farxiga or Jardiance approve Farxiga or Jardiance.

5. If the patient has a contraindication to metformin, according to the prescriber, approve Farxiga, or Jardiance.
   Note: Examples of contraindications to metformin include acute or chronic metabolic acidosis, including diabetic ketoacidosis.

6. If the patient has heart failure, approve Farxiga or Jardiance.

7. If the patient has chronic kidney disease, approve Farxiga or Jardiance.

8. If the patient has atherosclerotic cardiovascular disease or, according to the prescriber, the patient has at least two risk factors for cardiovascular disease, approve Farxiga or Jardiance.

Step 3 Products

1. If the patient has tried one Step 2 Product, approve a Step 3 Product.
   Note: A trial of a Step 1 Product is required prior to a Step 2 Product, unless exception criteria are met.

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Initial Approval/ Extended Approval.
A) *Initial Approval:* 2 years
B) *Extended Approval:* 2 years

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