

# Drug Policy

<b>Policy:</b>  <b>CC</b>	<b>Sodium Glucose Co-Transporter-2 (SGLT-2) Inhibitors Preferred Step Therapy Policy</b>	<b>Annual Review Date: 02/15/2024</b>  <b>Last Revised Date: 02/15/2024</b>
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## OVERVIEW

Farxiga, Invokana, and Jardiance 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. Farxiga is also indicated for both heart failure NYHA Class II-IV patients with reduced ejection fraction and patients with chronic kidney disease. SGLT-2 is expressed in the proximal renal tubules and is responsible for most reabsorption of filtered glucose from the tubular lumen. By inhibiting SGLT-2, Farxiga, Jardiance, and Steglatro reduce the reabsorption of filtered glucose and lower the renal threshold for glucose, thereby increasing urinary glucose excretion. Xigduo XR, Synjardy, Synjardy XR, Invokamet, Invokamet XR, and Segluromet are combination products containing an SGLT-2 inhibitor and metformin extended-release or metformin.

## 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:** Patients with a history of one Step 1 drug within the 130-day look-back period are excluded from step 2 therapy. 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.

**Step 1:** metformin, metformin-extended release, Fortamet ER, Glumetza ER, Riomet solution, Glucovance, glyburide-metformin, glipizide-metformin, ActoplusMet, pioglitazone-metformin, Avandamet, , Kazano, alogliptin/metformin, Jentadueto, Jentadueto XR, Kombiglyze XR, Janumet, Janumet XR.

**Step 2:** Farxiga, Jardiance, Xigduo XR, Synjardy, Synjardy XR, Segluromet, Steglatro.

## CRITERIA

1. If the patient has tried one Step 1 product, authorization for a Step 2 product may be given.
2. If the patient will be initiating dual-therapy with metformin AND a single-entity Step 2 sodium glucose co-transporter-2 (SGLT-2) inhibitor, approve a single-entity Step 2 SGLT-2 inhibitor.

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3. If the patient has been started on a Step 2 product, approve the requested Step 2 product (patients are not required to go back and try a Step 1 product).
4. For patients with established heart failure, approve Farxiga or Jardiance
5. For patients with chronic kidney disease (CKD), approve Farxiga or Jardiance

## **Initial Approval/ Extended Approval.**

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

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## **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.

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## 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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- Synjardy XR® tablets [prescribing information]. Ridgefield, CT and Indianapolis, IN: Boehringer Ingelheim Pharmaceuticals, Inc and Eli Lilly and Company; December 2016.
- Steglatro™ tablets [prescribing information]. Whitehouse Station, NJ: Merck; December 2017.
- Segluromet™ tablets [prescribing information]. Whitehouse Station, NJ: Merck; December 2017.