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5.30.059

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Endocrine and Metabolic Agents	**Original Policy Date:**	January 1, 2019
Subject:	SGLT2 Step Policy	**Page:**	1 of 8

Last Review Date: March 7, 2025

SGLT2 Step Policy

Description

Farxiga (dapagliflozin), Glyxambi (empagliflozin/linagliptin), Jardiance (empagliflozin), Qtern (dapagliflozin/saxagliptin), Synjardy, Synjardy XR (empagliflozin/metformin), Xigduo XR (dapagliflozin/metformin)

Background
Farxiga (dapagliflozin), Glyxambi (empagliflozin/linagliptin), Jardiance (empagliflozin), Qtern (dapagliflozin/saxagliptin), Synjardy, Synjardy XR (empagliflozin/metformin), and Xigduo XR (dapagliflozin/metformin) are oral sodium-glucose co-transporter 2 (SGLT2) inhibitors indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus. They should not be used to treat type 1 diabetes; in those who have increased ketones in their blood or urine (diabetic ketoacidosis); or in those with severe renal impairment, end stage renal disease, or in patients on dialysis. They work by blocking the reabsorption of glucose by the kidney, increasing glucose excretion, and lowering blood glucose levels in patients with diabetes who have elevated blood glucose levels. Farxiga and Jardiance are also indicated to reduce the risk of cardiovascular death and hospitalization for heart failure (HF). In addition, Farxiga and Jardiance are indicated to reduce the risk of kidney function decline, kidney failure, cardiovascular death, and hospitalization in adult patients with chronic kidney disease (1-7).

Regulatory Status

FDA-approved indications for Farxiga, Glyxambi, Jardiance, Qtern, Synjardy, Synjardy XR, and Xigduo XR: They are sodium-glucose co-transporter 2 (SGLT2) inhibitors indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (1-7).

Farxiga is also indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure, and to reduce the risk of sustained eGFR decline, end stage kidney disease cardiovascular death and hospitalization for heart failure in adults with chronic kidney disease at risk of progression (2).

Jardiance is also indicated to reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure, and to reduce the risk of sustained decline in eGFR, end stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression (1).

Synjardy and Synjardy XR are also indicated in adults with type 2 diabetes mellitus to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (5-6).

Limitations of Use for Farxiga and Jardiance for CKD: (1-2)
Farxiga and Jardiance are not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent of history of immunosuppressive therapy for the treatment of kidney disease. Farxiga and Jardiance are not expected to be effective in these populations.

The safety and effectiveness of Farxiga, Glyxambi, Qtern, Synjardy, Synjardy XR, and Xigduo XR in pediatric patients less than 18 years of age have not been established (2-7).

The safety and effectiveness of Jardiance in pediatric patients less than 10 years of age have not been established (1).

Related policies
GLP-1 Agonists, Insulin GLP-1 Combinations, Metformin, Mounjaro, SGLT2 Inhibitors, Trijardy XR

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Farxiga, Glyxambi, Jardiance, Qtern, Synjardy, Synjardy XR, and Xigduo XR may be considered **medically necessary** if the conditions indicated below are met.

Farxiga, Glyxambi, Jardiance, Qtern, Synjardy, Synjardy XR, and Xigduo XR may be considered **investigational** for all other indications.

Prior-Approval Requirements

*Claims submitted with an ICD 10 diagnosis code indicating type 2 diabetes mellitus **OR** patients who have filled metformin in the past 1 year are exempt from these Prior Authorization (PA) requirements.*

Diagnosis

Patient must have the following:

Type 2 diabetes mellitus (T2DM)
a. Patient has had an inadequate treatment response, intolerance, or contraindication to metformin
b. **NO** dual therapy with other SGLT2 inhibitors (see Appendix 1)

Farxiga and Jardiance only

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Heart failure (HF)
    a. **NO** dual therapy with other SGLT2 inhibitors (see Appendix 1)

2. Chronic kidney disease (CKD)
    a. **NO** polycystic kidney disease (PKD)
    b. **NO** current or recent history of immunosuppressive therapy for the treatment of kidney disease (e.g., tacrolimus, sirolimus, cyclosporine, mycophenolate etc.)

c. **NO** dual therapy with other SGLT2 inhibitors (see Appendix 1)

Prior – Approval *Renewal* Requirements

Diagnosis

Patient must have the following:

1. Type 2 diabetes mellitus (T2DM)
   a. **NO** dual therapy with other SGLT2 inhibitors (see Appendix 1)

Farxiga and Jardiance only

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Heart failure (HF)
   a. Symptoms have improved or stabilized
   b. **NO** dual therapy with other SGLT2 inhibitors (see Appendix 1)

2. Chronic kidney disease (CKD)
   a. Reduced decline in renal function
   b. **NO** dual therapy with other SGLT2 inhibitors (see Appendix 1)

Policy Guidelines

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Farxiga (dapagliflozin), Glyxambi (empagliflozin/linagliptin), Jardiance (empagliflozin), Qtern (dapagliflozin/saxagliptin), Synjardy, Synjardy XR (empagliflozin/metformin), and Xigduo XR (dapagliflozin/metformin) are oral sodium-glucose co-transporter 2 (SGLT2) inhibitors indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus. They should not be used to treat type 1 diabetes; in those who have increased ketones in their blood or urine (diabetic ketoacidosis); or in those with severe renal impairment, end stage renal disease, or in patients on dialysis. They work by blocking the reabsorption of glucose by the kidney, increasing glucose excretion, and lowering blood glucose levels in patients with diabetes who have elevated blood glucose levels. Farxiga and Jardiance are also indicated to reduce the risk of cardiovascular death and hospitalization for heart failure (HF). In addition, Farxiga and Jardiance are indicated to reduce the risk of kidney function decline, kidney failure, cardiovascular death, and hospitalization in adult patients with chronic kidney disease. The safety and effectiveness of Farxiga, Glyxambi, Qtern, Synjardy, Synjardy XR, and Xigduo XR in pediatric patients less than 18 years of age have not been established. The safety and effectiveness of Jardiance in pediatric patients less than 10 years of age have not been established (1-7).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Farxiga, Glyxambi, Jardiance, Qtern, Synjardy, Synjardy XR, and Xigduo XR while maintaining optimal therapeutic outcomes.

References

1. Jardiance [package insert]. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. September 2023.
2. Farxiga [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP.; June 2024.
3. Glyxambi [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2023.
4. Qtern [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2023.
5. Synjardy [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2023.
6. Synjardy XR [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2023.
7. Xigduo XR [package insert]. Wilmington, DE. AstraZeneca Pharmaceuticals LP.; April 2022.

Policy History

Date	Action
November 2018	Addition to PA
May 2019	Addition of Qternmet XR and revised lookback statement to only include metformin
June 2019	Annual review
June 2020	Annual review. Addition of Farxiga indication: heart failure. Revised requirements to include diagnosis of Type 2 diabetes mellitus
September 2020	Annual review
May 2021	Addition of Farxiga indication: chronic kidney disease.
July 2021	Added requirement for all indications: NO dual therapy with other SGLT2 inhibitors. Added Appendix 1.
September 2021	Annual review
October 2021	Addition of Jardiance indication: heart failure with reduced ejection fraction. Farxiga criteria revised: Updated diagnosis to heart failure with reduced ejection fraction, removed requirements for heart failure indication: ejection fraction ≤40%, 4 week prior treatment with ACE or ARB, used in combination with beta blocker or diuretic as tolerated, prescribed or recommended by cardiologist. Removed requirements for chronic kidney disease indication: used in combination with maximally tolerated dose of ACE or ARB unless medically contraindicated, prescribed or recommended by nephrologist; per FEP
December 2021	Annual review
March 2022	Removed “reduced ejection fraction” requirement for Jardiance per PI update
June 2022	Annual editorial review and reference update. Removed Qternmet from policy
March 2023	Per FEP, removed t/f metformin from renewal requirements for Type 2 DM. Changed policy number to 5.30.059
June 2023	Per PI update, removed “reduced ejection fraction” requirement for Farxiga
September 2023	Annual review. Added Inpefa to Appendix 1
October 2023	Added “claims submitted with an ICD 10 diagnosis code indicating type 2 diabetes mellitus” are exempt from PA requirements
December 2023	Annual review
January 2023	Per PI update, added indication of CKD to Jardiance
March 2024	Annual review. Per SME, changed renewal requirement for CKD to “reduced decline in renal function” from “eGFR has improved or stabilized”
September 2024	Annual review and reference update
March 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.

Appendix 1 - List of SGLT2 Inhibitors

Generic Name	Brand Name
bexagliflozin	Brenzavvy
canagliflozin	Invokana
canagliflozin/metformin	Invokamet/Invokamet XR
dapagliflozin	Farxiga
dapagliflozin/metformin	Xigduo XR
dapagliflozin/saxagliptin	Qtern
empagliflozin	Jardiance
empagliflozin/linagliptin	Glyxambi
empagliflozin/linagliptin/metformin	Trijardy XR
empagliflozin/metformin	Synjardy/Synjardy XR
ertugliflozin	Steglatro
ertugliflozin/metformin	Segluromet
ertugliflozin/sitagliptin	Steglujan
sotagliflozin	Inpefa