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Section:	Prescription Drugs	Effective Date:	July 1, 2022
Subsection:	Endocrine and Metabolic Agents	Original Policy Date:	January 1, 2019
Subject:	SGLT2 Step Policy	Page:	1 of 8

Last Review Date: June 16, 2022

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), Qternmet XR (dapagliflozin/saxagliptin/metformin), 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 adults 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). Farxiga alone is indicated to reduce the risk of kidney function decline, kidney failure, cardiovascular death, and hospitalization for heart failure in adult patients with chronic kidney disease (1-8).

Regulatory Status

FDA-approved indications for Farxiga, Glyxambi, Jardiance, Qtern, Qternmet XR, Synjardy, Synjardy XR, and Xigduo XR: They are sodium-glucose co-transporter 2 (SGLT2) inhibitors

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indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (1-8).

Farxiga is also indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure with reduced ejection fraction (NYHA class II-IV), 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 (1).

Limitations of Use for Farxiga for CKD: (2)

Farxiga is not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of immunosuppressive therapy for the treatment of kidney disease. Farxiga is not expected to be effective in these populations.

The safety and effectiveness of Farxiga, Glyxambi, Jardiance, Qtern, Qternmet XR, Synjardy, Synjardy XR, and Xigduo XR in pediatric patients less than 18 years of age have not been established (1-8).

Related policies

Metformin, SGLT2 Inhibitors

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, Qternmet XR, Synjardy, Synjardy XR, and Xigduo XR may be considered **medically necessary** for patients with type 2 diabetes mellitus who have had an inadequate response, intolerance or contraindication to metformin.

Farxiga may be considered **medically necessary** for patients with heart failure or chronic kidney disease and if the conditions indicated below are met.

Jardiance may be considered **medically necessary** for patients with heart failure and if the conditions indicated below are met.

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

Prior-Approval Requirements

Patients who have filled metformin in the past 1 year are exempt from these PA requirements.

Diagnosis

Patient must have the following:

Type 2 diabetes mellitus

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

Farxiga only

Age 18 years of age or older

Diagnoses

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

1. Heart failure with reduced ejection fraction (HFrEF)
 - a. NYHA activity class II – IV
 - b. **NO** dual therapy with other SGLT2 inhibitors (see Appendix 1)
2. Chronic kidney disease
 - a. **NO** polycystic kidney disease
 - 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)

Jardiance only

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Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Heart failure
 - a. **NO** dual therapy with other SGLT2 inhibitors (see Appendix 1)
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Prior – Approval *Renewal* Requirements

Diagnosis

Patient must have the following:

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

Farxiga only

Age 18 years of age or older

Diagnoses

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

1. Heart failure
 - a. Symptoms have improved or stabilized
 - b. **NO** dual therapy with other SGLT2 inhibitors (see Appendix 1)
2. Chronic kidney disease
 - a. eGFR has improved or stabilized
 - b. **NO** dual therapy with other SGLT2 inhibitors (see Appendix 1)

Jardiance only

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Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Heart failure
 - a. Symptoms have improved or stabilized
 - 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), Qternmet XR (dapagliflozin/saxagliptin/metformin), 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 adults 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 is also indicated to reduce the risk of cardiovascular death and hospitalization for heart failure (HF). Farxiga alone is indicated to reduce the risk of kidney function decline, kidney failure, cardiovascular death, and hospitalization for heart failure in adult patients with chronic kidney disease. The safety and effectiveness of Farxiga, Glyxambi,

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Jardiance, Qtern, Qternmet XR, Synjardy, Synjardy XR, and Xigduo XR in pediatric patients less than 18 years of age have not been established (1-8).

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

References

1. Jardiance [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc. March 2022.
2. Farxiga [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP.; April 2021.
3. Glyxambi [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; March 2022.
4. Qtern [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; March 2022.
5. Qternmet XR [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP.; January 2020.
6. Synjardy [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; March 2022.
7. Synjardy XR [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; March 2022.
8. 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

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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 $\leq 40\%$, 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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.

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Appendix 1 - List of SGLT2 Inhibitors

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