
5.30.019

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Subsection:	Endocrine and Metabolic Agents	Original Policy Date:	September 18, 2015
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Last Review Date: December 12, 2025

SGLT2 Inhibitors

Description

Brenzavvy (bexagliflozin)

Farxiga (**dapagliflozin**)

Glyxambi (empagliflozin/linagliptin)

Invokana (canagliflozin)

Invokamet, Invokamet XR (canagliflozin/metformin)

Jardiance (empagliflozin)

Segluromet (ertugliflozin/metformin)

Steglatro (ertugliflozin)

Steglujan (ertugliflozin/sitagliptin)

Synjardy, Synjardy XR (empagliflozin/metformin)

Xigduo XR (**dapagliflozin/metformin**)

Bolded medications are the preferred products.

Background

Oral sodium-glucose co-transporter 2 (SGLT2) inhibitors are 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 (1-13).

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Regulatory Status

FDA-approved indications for SGLT2 Inhibitors: (1-13)

- SGLT2 inhibitors are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- 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.
- Invokana, Invokamet, and Invokamet XR are also indicated to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.
- Invokana, Invokamet, and Invokamet XR are also indicated to reduce the risk of end-stage kidney disease, doubling of serum creatinine, cardiovascular death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria.
- 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.

Related policies

Antidiabetic GLP-1 GIP Agonists, Insulin GLP-1 Combinations, Metformin, 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.

SGLT2 inhibitors may be considered **medically necessary** if the conditions indicated below are met.

SGLT2 inhibitors may be considered **investigational** for all other indications.

Prior-Approval Requirements

Preferred SGLT2 Inhibitors only

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*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:

1. 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)
-

Non-preferred SGLT2 Inhibitors only

Age 18 years of age or older

Diagnosis

Patient must have the following with provided documentation (e.g., medical records, laboratory reports):

1. Type 2 diabetes mellitus
 - a. Inadequate treatment response, intolerance, or contraindication to metformin
 - b. **NO** dual therapy with other SGLT2 inhibitors (see Appendix 1)
 - c. Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Dapagliflozin, Farxiga, and Jardiance only

Age 18 years of age or older

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Diagnoses

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

1. Heart failure (HF)
 - a. **NO** dual therapy with other SGLT2 inhibitors (see Appendix 1)
 - b. **Brand Farxiga only:** Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
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)
 - d. **Brand Farxiga only:** Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Prior – Approval *Renewal* Requirements

Preferred SGLT2 Inhibitors only

Diagnosis

Patient must have the following:

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

Non-preferred SGLT2 Inhibitors only

Age 18 years of age or older

Diagnosis

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Patient must have the following with provided documentation (e.g., medical records, laboratory reports):

1. Type 2 diabetes mellitus
 - a. **NO** dual therapy with other SGLT2 inhibitors (see Appendix 1)
 - b. Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Dapagliflozin, 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)
 - c. **Brand Farxiga only:** Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
2. Chronic kidney disease (CKD)
 - a. Reduced decline in renal function
 - b. **NO** dual therapy with other SGLT2 inhibitors (see Appendix 1)
 - c. **Brand Farxiga only:** Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

SGLT2 inhibitors are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Renal function should be monitored during SGLT2 therapy. SGLT2 Inhibitors should not be used for treatment of type 1 diabetes mellitus or diabetic ketoacidosis. 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 (1-13).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of SGLT2 inhibitors while maintaining optimal therapeutic outcomes.

References

1. Brenzavvy [package insert]. Marlborough, MA: TheracosBio, LLC; 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. Invokana [package insert] Titusville, NJ: Janssen Pharmaceuticals, Inc.; July 2023.
5. Invokamet [package insert] Titusville, NJ: Janssen Pharmaceuticals, Inc.; January 2024.
6. Invokamet XR [package insert] Titusville, NJ: Janssen Pharmaceuticals, Inc.; January 2024.
7. Jardiance [package insert]. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. September 2023.
8. Steglatro [package insert] Whitehouse Station, NJ: Merck & Co., Inc.; June 2024.
9. Steglujan [package insert] Whitehouse Station, NJ: Merck & Co., Inc.; June 2024.
10. Segluromet [package insert] Whitehouse Station, NJ: Merck & Co., Inc.; June 2024.

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11. Synjardy [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2023.
12. Synjardy XR [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2023.
13. Xigduo XR [package insert]. Wilmington, DE. AstraZeneca Pharmaceuticals LP.; April 2022.

Policy History

Date	Action
September 2015	New addition to PA
December 2015	Annual editorial review and reference update
March 2016	Annual editorial review Addition of inadequate treatment response, intolerance, or contraindication to one of the following: alpha-glucosidase inhibitor, sulfonylurea, or thiazolidinedione; addition of eGFR 's for the different medications Changed the wording of weight loss to exclusively used for weight loss Policy number change from 5.07.19
September 2016	Annual editorial review and reference update
October 2016	Addition of Invokamet XR
December 2016	Annual review
January 2017	Addition of Synjardy XR
March 2017	Annual editorial review and reference update Addition of Qtern and the age requirement in the renewal section
June 2017	Annual editorial review Addition of dipeptidyl peptidase 4 inhibitors (DPP-4) and glucagon-like peptide-1 receptor agonists (GLP-1) to the tried and failed requirement Removal of sulfonylurea from the tried and failed requirement
January 2018	Addition of Steglatro, Steglujan, and Segluromet
March 2018	Annual editorial review Change in initiation criteria from: inadequate treatment response, intolerance, or contraindication to metformin monotherapy, to inadequate treatment response, intolerance, or contraindication to metformin.
June 2018	Annual review and reference update Addition of eGFR requirement to the renewal section and the removal of no severe renal impairment, ESRD, or on dialysis
November 2018	Annual editorial review and reference update. Updated Invokana, Invokamet, and Invokamet XR indications. Removed Step Edit SGLT2s

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	from policy: Farxiga, Qtern, Jardiance, Glyxambi, Synjardy, Synjardy XR, Xigduo XR
November 2019	Reduced Invokana 100 mg required eGFR from ≥ 45 to ≥ 30
December 2019	Annual review and reference update. Addition of requirement to trial preferred products
June 2020	Annual review and reference update
September 2020	Annual review. Revised eGFR limits for Invokana, Invokamet, and Invokamet XR and added the option of albuminuria > 300 mg/day for Invokana 100 mg. Also removed boxed warning statement for lower limb amputation for Invokana, Invokamet, and Invokamet XR
November 2020	Addition of Trijardy XR
January 2021	Removal of Trijardy XR to its own policy
March 2021	Annual review
October 2021	Revised eGFR limit for Steglatro, Steglujan, and Segluromet to ≥ 45 mL/min/1.73m ²
December 2021	Annual review
September 2022	Annual review and reference update. Addition of Appendix 1
September 2023	Annual review. Added Inpefa to Appendix 1
December 2023	Annual editorial review. Addition of Brenzavvy to policy
September 2024	Annual review and reference update
March 2025	Annual review
December 2025	Annual review. Added documentation requirement and dapagliflozin and dapagliflozin and metformin. Revised Appendix 2
June 2026	Added SGLT2 Step Policy medications back to this policy. Simplified criteria requirements for non-preferred medications. Added generic Farxiga and generic Xigduo XR to preferred medications and moved their brand names to non-preferred

Keywords

This policy was effective with interim approval on June 12, 2026 and will be reviewed by the FEP® Pharmacy and Medical Policy Committee on September 17, 2026.

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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
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

Appendix 2 - List of Preferred Products

List of preferred products:

https://info.caremark.com/content/dam/enterprise/caremark/microsites/dig/pdfs/pa-fep/fep-misc/FEP_ProductMedChx.pdf

Refer to formulary documents for confirmation of coverage:

<https://www.fepblue.org/pharmacy/prescriptions#drug-lists>