UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2022 P 2247-15
Program	Prior Authorization/Medical Necessity – Custom Oxford SoNY and SoCT - Diabetes Medications - SGLT2 Inhibitors
Medication	Farxiga (dapagliflozin)*, Glyxambi (empagliflozin/linagliptan), Invokana (canagliflozin)*, Invokamet (canagliflozin/metformin)*, Invokamet XR (canaglifloxin/metformin extended-release)*, Qtern (dapagliflozin/saxagliptin)*, Segluromet (ertugliflozin/metformin)*, Steglatro (ertugliflozin)*, Steglujan (ertugliflozin/sitagliptin)*, Xigduo XR (dapagliflozin/metformin extended-release)*
P&T Approval Date	10/2016, 10/2017, 4/2018, 8/2018, 12/2018, 2/2019, 3/2020, 5/2020, 7/2020, 7/2021, 10/2021, 2/2022, 4/2022, 8/2022, 9/2022
Effective Date	Oxford: 12/1/2022

1. Background:

Farxiga (dapagliflozin)*, Invokana (canagliflozin)*, Jardiance (empagliflozin) and Steglatro (ertugliflozin)* 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. Farxiga*, Invokana* and Jardiance have additional indications. Farxiga* is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction 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* is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD), and to reduce the risk of end-stage kidney disease (ESKD), doubling of serum creatinine, cardiovascular (CV) death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria > 300 mg/day. Jardiance is indicated to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease and to reduce the risk of cardiovascular death plus hospitalization for heart failure in adults.

Invokamet (canagliflozin/metformin)*, Invokamet XR (canagliflozin/metformin extended-release)*, Synjardy (empagliflozin/metformin), Synjardy XR (empagliflozin/metformin extended-release), Segluromet (ertugliflozin/metformin)*, and Xigduo XR (dapagliflozin/metformin extended-release)* are SGLT2 inhibitors and biguanide combination medications indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing metformin or a SGLT2 inhibitor or in patients already being treated with both a SGLT2 inhibitor and metformin.

Glyxambi (empagliflozin/linagliptan), Qtern (dapagliflozin/saxagliptin)* and Steglujan (ertugliflozin/sitagliptin)* are combination SGLT2 inhibitors and dipeptidyl peptidase-4 (DPP-4) inhibitors indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both a SGLT2 and a DPP4 inhibitor is appropriate.

If a member has a prescription for metformin orGlyxambi in the claims history within the previous 12 months, the claim for Glyxambi will automatically process. Members currently on Glyxambi as documented in claims history will be allowed continued coverage of their current therapy. Members new to therapy will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. Heart failure

1. **Farxiga*** will be approved based on the following criterion:

   a. History of therapeutic failure, contraindication or intolerance to a 30-day trial of Jardiance

   Authorization will be issued for 12 months.

B. Chronic kidney disease without diabetes

1. **Farxiga*** will be approved based on **both** of the following:

   a. History of suboptimal response, contraindication or intolerance to **one** of the following:

      1) Angiotensin converting enzyme (ACE) inhibitor (e.g., lisinopril)
      2) Angiotensin receptor blocker (e.g., losartan)

   -AND-

   b. History of therapeutic failure (after a three-month trial[b]), contraindication or intolerance to Jardiance

   Authorization will be issued for 12 months.

C. Chronic kidney disease with diabetes

1. **Farxiga* or Invokana*** will be approved based on the following criteria:

   a. History of suboptimal response, contraindication or intolerance to **one** of the following:

      1) Angiotensin converting enzyme (ACE) inhibitor (e.g., lisinopril)
      2) Angiotensin receptor blocker (e.g., losartan)

   -AND-

   b. History of suboptimal response (after a three-month trial[b]), contraindication or intolerance to metformin (generic Glucophage, Glucophage XR)

   -AND-

   c. History of therapeutic failure (after a three-month trial[b]), contraindication or intolerance to Jardiance

   Authorization will be issued for 12 months.

D. All other indications

1. **Glyxambi** will be approved based on **one** of the following criteria:

   a. History of suboptimal response (after a three-month trial[b]), contraindication or intolerance to metformin (generic Glucophage, Glucophage XR)

   -OR-

   b Currently on therapy with Glyxambi and is requesting continuation of the same therapy.

   Authorization will be issued for 12 months.

2. **Farxiga*, Invokana* or Steglatro*** will be approved based on the following criteria:

   a. History of suboptimal response (after a three-month trial[b]), contraindication or intolerance to metformin (generic Glucophage, Glucophage XR)

   -AND-

   b. History of therapeutic failure (after a three-month trial[b]), contraindication or intolerance to Jardiance

   Authorization will be issued for 12 months.

3. **Invokamet*, Invokamet XR*, Xigduo XR*, or Segluromet*** will be approved based on the following criterion:

   a. History of therapeutic failure (after a three-month trial[b]), contraindication or intolerance to Synjardy/Synjardy XR

   Authorization will be issued for 12 months.

4. **Qtern* or Steglujan*** will be approved based on the following criteria:

   a. History of suboptimal response (after a three-month trial[b]), contraindication or intolerance to metformin (generic Glucophage, Glucophage XR)

   -AND-

   b. History of therapeutic failure (after a three-month trial[b]), contraindication or intolerance to Glyxambi

   Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

[b] For Connecticut business, only a 60 day trial will be required.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may be in place.
- Prior Authorization – Medical Necessity may be in place

* Farxiga, Invokana, Invokamet, Invokamet XR, Qtern, Segluromet, Steglatro, Steglujan and Xigduo XR are typically excluded from coverage. Tried/failed criteria may be in place. Please refer to plan specifics to determine coverage status.

4. References:

1. Jardiance [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; March 2022.
2. Invokana [package insert] Titusville, NJ: Janssen Pharmaceuticals, Inc; November 2021
3. Farxiga [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP.; May 2021.
4. Steglatro [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; May 2022.
5. Invokamet/Invokamet XR [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; November 2021.
6. Synjardy/Synjardy XR [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; March 2022.
7. Segluromet [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; May 2022.
8. Xigduo XR [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP.;April 2022.
9. Glyxambi [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceutials, Inc.; March 2022.
10. Qtern [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP.; March 2022.
11. Steglujan [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; June 2022.
12. American Diabetes Association. Standard of Medical Care in Diabetes- 2022. *Diabetes Care* 2022;45 (Supplement 1)
13. Heidenreich, PA, Bozkurt B, Aguilar, D, et. al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 145; 2022: 895-1032.
14. KDIGO 2020 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. 2020; 98 (4S).
15. Zannad, F, Ferreira, JP, Pocock, SJ, et. al. Cardiac and Kidney Benefits of Empagliflozin in Heart Failure Across the Spectrum of Kidney Function. *Circulation*. 2021; 143:310-21.

Program	Prior Authorization/Medical Necessity – Diabetes Medication - SGLT2 Inhibitors
Change Control	
Date	Change
10/2016	New. Replaces Diabetes Medications program P1025 originally P&T approved 11/2012.
10/2017	Added Synjardy/Synjardy XR as step 1 agent for Xigduo XR. Updated references.

4/2018	Added Qtern, Segluromet, Steglatro and Steglujan as step 2 agents. Updated references.
8/2018	Modified the step criteria for Glyxambi to only require metformin, a sulfonylurea or a thiazolidinedione.
12/2018	Removed the sulfonylurea and thiazolidinedione requirement. Updated references.
2/2019	Modified the Qtern and Steglujan step.
3/2020	Annual review. Updated the background section and references.
5/2020	Invokana removed from the automated lookback. Added step requirement for Invokana, Invokamet, Invokamet XR. Updated references.
7/2020	Added step requirements for heart failure indication.
7/2021	Annual review. Updated background. Modified criteria for SGLT-2 inhibitors for heart failure. Updated failure language to remove reference to trial. Program type changed from Prior Authorization/Notification (P 1200-9) to Prior Authorization/Medical Necessity (P 2247-10).
10/2021	Added step requirement for chronic kidney disease. Updated failure to suboptimal response for heart failure section A and for metformin sections. Updated state mandate language for CT and KY. Updated references.
2/2022	Added Jardiance into the criteria for chronic kidney disease. Updated references.
4/2022	Jardiance label updated for heart failure with or without a reduced ejection fraction. Added section to allow for Jardiance for heart failure with preserved ejection fraction.
8/2022	Combined reduced and preserved heart failure sections and removed the step component. Farxiga will still require a step through Jardiance. Updated references.
10/2022	Removed Jardiance from targeted medications.