UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2020 P 1200-9 |
| Program | Prior Authorization/Notification – 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)*, Jardiance (empagliflozin), 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 |
| Effective Date | Oxford: 10/1/2020 |

## 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. 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.

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, Glyxambi or Jardiance in the claims history within the previous 12 months, the claim for Glyxambi or Jardiance will automatically process.

Members currently on Glyxambi, or Jardiance 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 with a reduced ejection fraction**

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

   a. History of a trial resulting in therapeutic failure, contraindication or intolerance to **three** of the following:

      1) Angiotensin converting enzyme (ACE) inhibitor (e.g., lisinopril)
      2) Angiotensin receptor blocker (e.g., losartan)
      3) Angiotensin receptor blocker/neprilysin inhibitor (i.e., Entresto)
      4) Beta-blocker (e.g., metoprolol)
      5) Diuretic (e.g., furosemide)
      6) Spironolactone

      -AND-

   b. History of a trial resulting in therapeutic failure, contraindication or intolerance to Jardiance

**Authorization will be issued for 12 months.**

2. **Jardiance** will be approved based on the following criteria:

   a. History of a trial resulting in therapeutic failure, contraindication or intolerance to **three** of the following:

      1) Angiotensin converting enzyme (ACE) inhibitor (e.g., lisinopril)
      2) Angiotensin receptor blocker (ARB) (e.g., losartan)
      3) Angiotensin receptor blocker/neprilysin inhibitor (i.e., Entresto)
      4) Beta-blocker (e.g., metoprolol)
      5) Diuretic (e.g., furosemide)
      6) Spironolactone

**Authorization will be issued for 12 months.**

**B. All other indications**

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

a. History of failure, contraindication or intolerance to metformin (generic Glucophage, Glucophage XR)

**-OR-**

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

**Authorization will be issued for 12 months.**

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

   a. History of a three month trial resulting in therapeutic failure, contraindication or intolerance to **both** of the following:

      1. Metformin (generic Glucophage, Glucophage XR)

      **-AND-**

      2. Jardiance

**Authorization will be issued for 12 months.**

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

   a. History of a three month trial resulting in therapeutic failure, contraindication or intolerance to Synjardy/Synjardy XR

**Authorization will be issued for 12 months.**

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

   a. History of a three month trial resulting in therapeutic failure, contraindication or intolerance to **both** of the following:

      1. Metformin (generic Glucophage, Glucophage XR)

      **-AND-**

      2. 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.

***Typically excluded from coverage**

**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.; January 2020.
2. Invokana [package insert] Titusville, NJ: Janssen Pharmaceuticals, Inc; January 2020.
3. Farxiga [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP.; May 2020.
4. Steglatro [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2020.
5. Invokamet/Invokamet XR [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; January 2020.
6. Synjardy/Synjardy XR [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; January 2020.
7. Segluromet [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2020.
8. Xigduo XR [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP.;February 2020.
9. Glyxambi [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceutials, Inc.; March 2020.
10. Qtern [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP.; January 2020.
11. Steglujan [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2020.
12. American Diabetes Association. Standard of Medical Care in Diabetes- 2019. *Diabetes Care* 2020;43 (Supplement 1)

13. Yancy, CW, Jessup, M, Bozkurt, B, et.al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. Circulation. 2017; 136(6): e137-61.

| Program | Notification – 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. |