Program Number | 2020 P 3086-7
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Program | Step Therapy – Diabetes Medications - SGLT2 Inhibitors
Medication | Farxiga (dapagliflozin)*, Glyxambi (empagliflozin/linagliptan), Invokana (canagliflozin), Jardiance (empagliflozin), Qtern (dapagliflozin/saxagliptin)*, Segluromet (ertugliflozin/metformin)*, Steglatro (ertugliflozin)*, Steglujan (ertugliflozin/sitagliptin)*, Xigduo XR (dapagliflozin/metformin extended-release)*
Effective Date | 5/1/2020; Oxford only: 5/1/2020

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 hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors. 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, Invokana or Jardiance in the claims history within the previous 12 months, the claim for Glyxambi, Invokana or Jardiance will automatically process. Members currently on Glyxambi, Invokana 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**

**Authorization**

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

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

   **-OR-**

2. **Both** of the following:

   a. Currently on therapy with Glyxambi, Invokana or Jardiance and is requesting continuation of the same therapy.

   **-AND-**

   b. **One** of the following:

      (1) Has **not** received a manufacturer supplied sample at no cost as a means to establish as a current user of Glyxambi, Invokana or Jardiance.

      **-OR-**

      (2) **Both** of the following:

         i. Has received a manufacturer supplied sample at no cost as a means to establish as a current user of Glyxambi, Invokana or Jardiance

         **-AND-**

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

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

**B. Farxiga* and Steglatro*** will be approved based on the following criteria:

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

   a. Metformin (generic Glucophage, Glucophage XR)

   **-AND-**
b. **Both** of the following:
   (1) Invokana
   (2) Jardiance

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

C. **Xigduo XR**, Segluromet* will be approved based on the following criterion:

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

   a. Invokamet/Invokamet XR
   b. Synjardy/Synjardy XR

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

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

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

   a. Metformin (generic Glucophage, Glucophage XR)
   -AND-
   b. 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.

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

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specifics to determine coverage status.

4. References:

8. Xigduo XR [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP.; October 2019.

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<tr>
<td><strong>Change Control</strong></td>
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<tr>
<td>Date</td>
<td>Change</td>
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<tr>
<td>10/2017</td>
<td>Added Synjardy/Synjardy XR as step 1 agent for Xigduo XR. Updated references.</td>
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<tr>
<td>4/2018</td>
<td>Added Qtern, Segluromet, Steglatro and Steglujan as step 2 agents. Updated references.</td>
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<tr>
<td>8/2018</td>
<td>Modified the step criteria for Glyxambi to only require metformin, a sulfonylurea or a thiazolidinedione.</td>
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<tr>
<td>12/2018</td>
<td>Removed the sulfonylurea and thiazolidinedione requirement. Updated references.</td>
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<tr>
<td>2/2019</td>
<td>Modified the Qtern and Steglujan step.</td>
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<tr>
<td>2/2020</td>
<td>Annual review. Updated the background section and references.</td>
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