UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1200-4
Program	Prior Authorization/Notification – Custom Oxford SoNY and SoCT - 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)*
P&T Approval Date	10/2016, 10/2017, 4/2018, 8/2018
Effective Date	Oxford: 1/1/2019

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.

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, a sulfonylurea, or a thiazolidinedione and has a prescription for 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[a]:

Authorization

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

1. History of failure, contraindication or intolerance to **one** of the following:

   a. Metformin (generic Glucophage, Glucophage XR)
   b. Sulfonylurea (e.g. glimepiride)
   c. Thiazolidinedione (e.g. pioglitazone)

-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 **one** of the following:
            - Metformin (generic Glucophage, Glucophage XR)
            - Sulfonylurea (e.g. glimepiride)
            - Thiazolindinedione (e.g. rosiglitazone)

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. **One** of the following:
(1) Metformin (generic Glucophage, Glucophage XR)
(2) Sulfonylurea (e.g. glimepiride)
(3) Thiazolidinedione (e.g. pioglitazone)

-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 **one** of the following:

a. **Both** of the following:

(1) **One** of the following:

(a) Metformin (generic Glucophage, Glucophage XR)
(b) Sulfonylurea (e.g., glimepiride)
(c) Thiazolidinedione (e.g., pioglitazone)

-AND-

(2) Glyxambi

-OR-

b. All of the following:

(1) **One** of the following:

(a) Metformin (generic Glucophage, Glucophage XR)
(b) Sulfonylurea (e.g., glimepiride)
(c) Thiazolidinedione (e.g., pioglitazone)

-AND-

(2) **One of the following:**
(a) Jardiance
(b) Invokana

-AND-

(3) **One of the following:**
(a) Nesina
(b) Onglyza
(c) Tradjenta

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 specifics to determine coverage status.

4. References:

1. Jardiance prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. December 2017.
2. Invokana Prescribing Information. Janssen Pharmaceuticals, Inc. Titusville, NJ. July 2017.
3. Farxiga Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. October 2017.
4. Steglatro prescribing information. Merck & Co., Inc. Whitehouse Station, NJ. December 2017.
5. Invokamet/Invokamet XR prescribing information. Janssen Pharmaceuticals, Inc. Titusville, NJ. January 2018.

6. Synjardy/Synjardy XR prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. December 2017.
7. Segluromet prescribing information. Merck & Co., Inc. Whitehouse Station, NJ. December 2017.
8. Xigduo XR prescribing information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. July 2017.
9. Glyxambi prescribing information. Boehringer Ingelheim Pharmaceutials, Inc. Ridgefield, CT. December 2017.
10. Qtern prescribing information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. February 2017.
11. Steglujan prescribing information. Merck & Co., Inc. Whitehouse Station, NJ. February 2018.
12. American Diabetes Association; Executive Summary: Standards of Medical Care in Diabetes 2012, Diabetes Care 2012:35:S4-S10.

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.