UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for SGLT-2 Inhibitors

Program	Prior Authorization
Medication	Invokana (canagliflozin), Farxiga (dapagliflozin), Jardiance (empagliflozin), Invokamet (canagliflozin/metformin), Xigduo XR (dapagliflozin/metformin extended release), Synjardy (empagliflozin/metformin), Invokamet XR (canagliflozin/metformin extended release), Synjardy XR (empagliflozin/metformin extended release), Steglatro (ertugliflozin), Segluromet (ertugliflozin/metformin)
Markets in Scope	California, Hawaii, Maryland, Nevada, New Jersey, New York, Pennsylvania- CHIP, South Carolina
Issue Date	12/2014
Pharmacy and Therapeutics Approval Date	10/2020
Effective Date	1/2021

1. Background:

Steglatro is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Segluromet is 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 ertugliflozin or metformin or in patients who are already treated with both ertugliflozin and metformin.

Jardiance is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Jardiance is also indicated to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease.

Invokana is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Invokana is also indicated to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease. Additionally, Invokana is 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.

Farxiga is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Additionally, Farxiga is indicated to reduce the risk

of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors. Farxiga is also indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure with reduced ejection fraction (NYHA class II-IV).

Synjardy and Synjardy XR are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and metformin is appropriate.

Invokamet and Invokamet XR are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both canagliflozin and metformin is appropriate.

Xigduo XR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both dapagliflozin and metformin is appropriate.

2. Coverage Criteria:

A. <u>Steglatro or Segluromet</u>

1. The patient has a diagnosis of type 2 diabetes mellitus

-AND-

2. History of failure to metformin at a minimum dose of 1500mg daily for 90 days, or contraindication or intolerance to metformin.

Authorization will be issued for 12 months.

B. <u>Jardiance</u>

1. The patient has a diagnosis of type 2 diabetes mellitus

-AND-

2. History of failure to metformin at a minimum dose of 1500mg daily for 90 days, or contraindication or intolerance to metformin.

-AND-

3. **<u>One</u>** of the following:

a. History of failure to Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin) for 90 days, or contraindication or intolerance to Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin).

-OR-

b. **Both** of the following

i. **One** of the following
   a) Documented history of heart failure
   b) Documented history of chronic kidney disease
   c) Documented history of atherosclerotic cardiovascular disease defined as having one or more of the following:
      - History of an acute coronary syndrome or myocardial infarction
      - Stable or unstable angina
      - Coronary heart disease with or without revascularization
      - Other arterial revascularization
      - Stroke
      - Peripheral artery disease assumed to be atherosclerotic in origin

-AND-

ii. History of failure to Farxiga (dapagliflozin)for 90 days, or contraindication or intolerance to Farxiga (dapagliflozin).

Authorization will be issued for 12 months.

C. Invokana

1. The patient has a diagnosis of type 2 diabetes mellitus

-AND-

2. History of failure to metformin at a minimum dose of 1500mg daily for 90 days, or contraindication or intolerance to metformin.

-AND-

3. **One** of the following:

a. History of failure to Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin) for 90 days, or contraindication or intolerance to Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin).

-OR-

b. Documented history of diabetic nephropathy with albuminuria >300mg/day

-OR-

c. **Both** of the following

i. **One** of the following
   a) Documented history of heart failure
   b) Documented history of chronic kidney disease
   c) Documented history of atherosclerotic cardiovascular disease defined as having one or more of the following:
      - History of an acute coronary syndrome or myocardial infarction
      - Stable or unstable angina
      - Coronary heart disease with or without revascularization
      - Other arterial revascularization
      - Stroke
      - Peripheral artery disease assumed to be atherosclerotic in origin

-AND-

ii. History of failure to Farxiga (dapagliflozin) for 90 days, or contraindication or intolerance to Farxiga (dapagliflozin)

Authorization will be issued for 12 months.

D. Farxiga

1. **One** of the following

a. **All** of the following
   i. The patient has a diagnosis of type 2 diabetes mellitus

-AND-

ii. History of failure to metformin at a minimum dose of 1500mg daily for 90 days, or contraindication or intolerance to metformin.

-AND-

iii. **One** of the following:
   a) Documented history of heart failure
   b) Documented history of chronic kidney disease
   c) Documented history of atherosclerotic cardiovascular disease defined as having one or more of the following:
      - History of an acute coronary syndrome or myocardial infarction
      - Stable or unstable angina
      - Coronary heart disease with or without revascularization
      - Other arterial revascularization
      - Stroke
      - Peripheral artery disease assumed to be atherosclerotic in origin
   d) **Two** of the following risk factors for developing cardiovascular disease:
      - Men ≥55 years and women ≥65 years
      - Cigarette smoker or stopped smoking within the past 3 months
      - Hypertension (pretreatment blood pressure ≥140 mmHg systolic or ≥90 mmHg diastolic)
      - HDL-C ≤40 mg/dL for men or ≤50 mg/dL for women
      - High-sensitivity C-reactive protein >3.0 mg/L
      - Creatinine clearance >30 and <60 mL/min
      - Retinopathy
      - Micro- or macro-albuminuria
      - Ankle-brachial index (ABI) <0.9 without symptoms of intermittent claudication
   e) History of failure to Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin) for 90 days, or contraindication or intolerance to Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin).

-OR-

b. **All** of the following:

i. The patient has a diagnosis of heart failure (NYHA class II-IV) **(note: if patient has both heart failure AND diabetes type 2, use criteria in section a)**

-AND-

ii. Patient has reduced ejection fraction defined as left ventricular ejection fraction (LVEF) 40% or less

-AND-

iii. History of failure, contraindication or intolerance to at least **three** of the following.
   a) Angiotensin converting enzyme (ACE) inhibitor (e.g., lisinopril)
   b) Angiotensin receptor blocker (e.g., losartan)
   c) Angiotensin receptor blocker/neprilysin inhibitor (i.e., Entresto)
   d) Beta-blocker (e.g., metoprolol)
   e) Diuretic (e.g., furosemide)
   e) Spironolactone

Authorization will be issued for 12 months.

E. Synjardy, Synjardy XR, Invokamet, Invokamet XR or Xigduo XR

1. The patient has a diagnosis of type 2 diabetes mellitus

-AND-

2. History of failure to metformin at a minimum dose of 1500mg daily for 90 days.

-AND-

3. History of failure to Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin) for 90 days, or contraindication or intolerance to Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin).

Authorization will be issued for 12 months.

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.

4. References:

1. Invokana[package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; August 2020.
2. Farxiga [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2020.
3. Invokamet/Invokamet XR [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; August 2020.
4. Jardiance [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; January 2020.
5. Xigduo XR [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; January 2020.
6. Synjardy/Synjardy XR [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; January 2020.
7. Steglatro [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2020.
8. Segluromet [package insert]. Whitehouse Station: NJ: Merck & Co., Inc.; January 2020.
9. American Diabetes Association. Standard of Medical Care in Diabetes- 2019. *Diabetes Care* 2020;43 (Supplement 1)
10. Davies MJ, et al; Management of hyperglycaemia in type 2 diabetes, 2018. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD), Diabetologia 2018.

Program	Prior Authorization –SGLT-2
Change Control	
Date	Change
12/2014	New policy
12/2015	Added Synjardy to policy Synjardy added to preferred drug trial requirements in the non-preferred criteria section
10/2016	Added authorization durations and updated policy template
2/2017	Added Invokamet XR and Synjardy XR to the policy.
4/2018	Added Steglatro and Segluromet to the policy. Updated background and references. Updated preferred and non-preferred products for 7/1/18 PDL changes.
7/2019	Updated program to reflect changes in 2018 ADA/EASD guidelines, including a pathway for approval for Invokana and

	Jardiance for patients with cardiovascular disease and chronic kidney disease.
11/2019	Updated criteria for Invokana for new indication for diabetic nephropathy.
5/2020	Updated criteria for Farxiga for new indication for cardiovascular disease.
10/2020	Added heart failure diagnosis for Farxiga. Added step through of Farxiga for Invoakan/Jardiance if patient has diabetes plus heart/kidney risk factors. Updated references.