



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1315-6
Program	Non-Formulary
Medication	Invokana [®] (canagliflozin)
P&T Approval Date	5/2020, 5/2021, 10/2021, 2/2022, 2/2023, 2/2024
Effective Date	5/1/2024

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, 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, to reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure with reduced ejection fraction and to reduce the risk of sustained decline in eGFR, end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression.

2. Coverage Criteria:

A. Initial Authorization

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

a. Diagnosis of type 2 diabetes mellitus

-AND-

b. Diagnosis of diabetic nephropathy with albuminuria > 300 mg/day^a

-AND-

c. Provider attests that Jardiance isn't a suitable treatment option^a

-AND-

- d. Submission of medical records (laboratory and clinical documentation) confirming diagnosis of kidney disease^a

Authorization will be issued for 12 months.

B. Reauthorization^a

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

- a. Documentation of a positive clinical response to Invokana therapy

Authorization will be issued for 12 months.

^a In Florida, Maine, and Tennessee only, medications prescribed for diabetes may be approved based on both of the following: 1) Provider attests use of this product is medically necessary for the treatment of diabetes; and- 2) If applicable, clinical characteristics exist that preclude the use of the covered preferred alternative(s) and use of the covered preferred alternative(s) could result in worsening of patient's condition or inadequate treatment (document alternatives and clinical information related to worsening/inadequate treatment).

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. Jardiance [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.;September 2023.
2. Invokana [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; July 2023.
3. Farxiga [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP.; September 2023.
4. Steglatro [package insert]. Rahway, NJ: Merck & Co., Inc.; September 2023.
5. American Diabetes Association. Standard of Medical Care in Diabetes- 2023. Diabetes Care 2023;46 (Supplement 1).
6. de Boer, IH, Khunti, K, Sadusky, T, et al. Diabetes Management in Chronic Kidney Disease: A Consensus Report by the American Diabetes Association (ADA) and Kidney Disease: Improving Global Outcomes (KDIGO). Diabetes Care 2022.
7. KDIGO 2022 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. 2022. 102 (5S).

Program	NonFormulary – Invokana
Change Control	
Date	Change
5/2020	New program.
5/2021	Annual review. Updated background section and references.
10/2021	Updated background and references.
2/2022	Added Florida, Maine, and Tennessee mandate language. Updated references.
2/2023	Annual review. Updated references.
2/2024	Annual review. Updated background section, references and diabetes footnote.