Drug Quantity Management Policy – Per Rx

Policy: Diabetes – Canagliflozin Products Drug Quantity Management Policy – Per Rx
- Invokana® (canagliflozin tablets – Janssen)
- Invokamet® (canagliflozin and metformin HCl tablets – Janssen)
- Invokamet® XR (canagliflozin and metformin HCl extended-release tablets – Janssen)

Review Date: 06/03/2025

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna National Formulary Coverage:

Overview

Invokana, Invokamet, and Invokamet XR are products that all contain canagliflozin, a sodium-glucose co-transporter-2 (SGLT-2) inhibitor.[1] Invokamet and Invokamet XR are combination products that contain canagliflozin in combination with metformin.[2] These agents are indicated as an adjunct to diet and exercise to **improve glycemic control** in adults and pediatric patients ≥ 10 years of age with **Type 2 diabetes mellitus**.[1,2]

The canagliflozin component, specifically, is indicated in patients with **Type 2 diabetes mellitus**:

- To **reduce the risk of major adverse cardiovascular events** in adults with established cardiovascular disease.
- To **reduce the risk of end-stage kidney disease, doubling of serum creatinine, cardiovascular death, and hospitalization for heart failure** in adults with diabetic nephropathy with albuminuria > 300 mg/day.

Limitation of Use: Invokana is not recommended for use in patients with Type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients. Invokana is not recommended for use to improve glycemic control in adults with Type 2 diabetes mellitus with an estimated glomerular filtration rate (eGFR) less than 30 mL/min/1.73m^2. Invokana is likely to be ineffective in this setting based upon its mechanism of action.

Dosing

Invokana

The recommended dose of Invokana for glycemic control is 100 mg once daily (QD).[1] The dose may be increased to 300 mg QD if needed for additional glycemic control. Dose reductions may be needed for patients with renal dysfunction.

Invokamet/Invokamet XR

Invokamet is dosed as one tablet twice daily (BID) and Invokamet XR is dosed as two tablets QD, with the initial and maintenance dosing based on the patient's renal function and current medication regimen.[2] Following initial dosing, if patients require additional glycemic control, the dose can be titrated up, to a maximum daily dose of canagliflozin 300 mg and metformin HCl 2,000 mg, in patients with an eGFR of at least 60 mL/min/1.73m^2. For patients with renal impairment, the maximum recommended dose is lower. Initiation of Invokamet or Invokamet XR is not recommended in patients with an eGFR < 45 mL/min/1.73 m^2, due to the metformin component.

Drug Interactions

If the patient is taking a canagliflozin product with a UDP-glucuronosyltransferase (UGT) inducer (e.g., rifampin, phenytoin, phenobarbital, ritonavir), the total daily dose should be increased from 100 mg to 200 mg.[1,2] If the patient has an eGFR ≥ 60 mL/min/1.73 m^2, the daily dose may be further increased to 300 mg, if needed for additional glycemic control.

Availability

Invokana is available as 100 mg tablets and 300 mg tablets in bottles of 30 or 90 tablets.[1]

Invokamet and Invokamet XR are each available as tablets containing 50 mg/500 mg, 50 mg/1,000 mg, 150 mg/500 mg, and 150 mg/1,000 mg of canagliflozin/metformin, respectively, supplied in bottles of 60 tablets.[2] Invokamet XR differs from Invokamet in that it provides canagliflozin for immediate-release and metformin HCl for extended-release.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of the canagliflozin products. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Strength	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Invokana® (canagliflozin tablets)	100 mg tablets	30 tablets	90 tablets
	300 mg tablets	30 tablets	90 tablets
Invokamet® (canagliflozin and metformin HCl tablets)	50 mg/500 mg tablets	60 tablets	180 tablets
	50 mg/1,000 mg tablets	60 tablets	180 tablets
	150 mg/500 mg tablets	60 tablets	180 tablets
	150 mg/1,000 mg tablets	60 tablets	180 tablets
Invokamet® XR (canagliflozin and metformin HCl extended-release tablets)	50 mg/500 mg tablets	60 tablets	180 tablets
	50 mg/1,000 mg tablets	60 tablets	180 tablets
	150 mg/500 mg tablets	60 tablets	180 tablets
	150 mg/1,000 mg tablets	60 tablets	180 tablets

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

Invokana 100 mg tablets

1. If the patient is taking Invokana with a UDP-glucuronosyltransferase (UGT) inducer approve 60 tablets per dispensing at retail or 180 tablets per dispensing at home delivery.
   Note: Examples of UGT inducers include rifampin, phenytoin, phenobarbital, and ritonavir.

Invokana 300 mg tablets

No overrides recommended.

Invokamet 50 mg/500 mg tablets

1. If the patient is taking Invokamet with a UDP-glucuronosyltransferase (UGT) inducer, approve 120 tablets per dispensing at retail or 360 tablets per dispensing at home delivery.
Note: Examples of UGT inducers include rifampin, phenytoin, phenobarbital, and ritonavir.

Invokamet 50 mg/1,000 mg tablets
No overrides recommended.

Invokamet 150 mg/500 mg tablets
No overrides recommended.

Invokamet 150 mg/1,000 mg tablets
No overrides recommended.

Invokamet XR 50 mg/500 mg tablets

1. If the patient is taking Invokamet XR with a UDP-glucuronosyltransferase (UGT) inducer, approve 120 tablets per dispensing at retail or 360 tablets per dispensing at home delivery.
Note: Examples of UGT inducers include rifampin, phenytoin, phenobarbital, and ritonavir.

Invokamet XR 50 mg/1,000 mg tablets
No overrides recommended.

Invokamet XR 150 mg/500 mg tablets
No overrides recommended.

Invokamet XR 150 mg/1,000 mg tablets
No overrides recommended.

REFERENCES

1. Invokana® tablets [prescribing information]. Titusville, NJ: Janssen; December 2024.
2. Invokamet® tablets/Invokamet® XR extended-release tablets [prescribing information]. Titusville, NJ: Janssen; December 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. No criteria changes.	06/01/2023
Annual Revision	No criteria changes.	06/03/2024
Annual Revision	No criteria changes.	06/03/2025