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: 06/01/2022

OVERVIEW

Invokama, Invokamet, and Invokamet XR are products that all contain canagliflozin, a sodium-glucose cotransporter-2 (SGLT-2) inhibitor. Invokamet and Invokamet XR are combination products that contain canagliflozin in combination with metformin HCl. These agents are indicated as an adjunct to diet and exercise to **improve glycemic control** in adults with **Type 2 diabetes mellitus**. 1.2

Canagliflozin, 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.

<u>Limitation of Use</u>: 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/1.73m². 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 60 mL/min/1.73m². For patients with renal impairment, the maximum recommended dose is lower.

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 \geq 60 mL/min/1.73 m², 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.

Automation: None.

Drug Quantity Limits

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

CRITERIA

Invokana 100 mg tablets

1. If the patient is taking Invokana with a UDP-glucuronosyltransferase (UGT) inducer approve 60 tablets per dispensing.

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.

Note: Examples of UGT inducers include rifampin, phenytoin, phenobarbital, and ritonavir.

Invokamet 50 mg/1,000 mg tablets

No overrides recommended.

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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.

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; August 2020.
- 2. Invokamet® tablets/Invokamet® XR extended-release tablets [prescribing information]. Titusville, NJ: Janssen; August 2020.