

Drug Policy

Policy:	Inpefa (sotagliflozin)	Annual Review Date: 09/19/2024 Last Revised Date: 09/19/2024
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OVERVIEW

Inpefa, a sodium glucose co-transporter-2 (SGLT-2) inhibitor, is indicated **to reduce the risk of cardiovascular (CV) death, hospitalization for heart failure (HHF), and urgent heart failure visit in adults** with¹:

- Heart failure; OR
- Type 2 diabetes mellitus, chronic kidney disease (CKD), and other CV risk factors.

Unlike other SGLT-2 inhibitors, Inpefa is not indicated for glycemic control.

POLICY STATEMENT

This policy involves the use of Inpefa. Prior authorization is recommended for pharmacy benefit coverage of Inpefa. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Inpefa is recommended in those who meet the following criteria:

1. **Heart Failure, to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit.** *Approve if the patient is ≥ 18 years of age.*
2. **Type 2 Diabetes, to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit.**
Criteria. *Patient must meet the following criteria (A, B, and C):*
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has chronic kidney disease; AND
 - C) Patient has one or more cardiovascular risk factor(s), according to the prescriber.**Note:** Patients with heart failure should be reviewed under criteria for *Heart Failure*.

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Initial Approval/ Extended Approval.

A) *Initial Approval:* 1 year

B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Inpefa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Type 1 Diabetes.** Inpefa is not approved for glycemic control. Note: Patients with heart failure should be reviewed under criteria for Heart Failure.
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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