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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Cardiovascular Agents	**Original Policy Date:**	August 4, 2023
Subject:	Inpefa	**Page:**	1 of 5

Last Review Date: March 8, 2024

Inpefa

Description

Inpefa (sotagliflozin)

Background
Inpefa (sotagliflozin) is a sodium-glucose cotransporter 2 (SGLT2) and SGLT1 inhibitor. Inhibiting SGLT2 reduces renal reabsorption of glucose and sodium which may influence several physiological functions such as lowering both pre-and afterload of the heart and downregulating sympathetic activity. Inhibiting SGLT1 reduces intestinal absorption of glucose (1).

Regulatory Status
FDA-approved indications: Inpefa is an SGLT2 inhibitor indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with (1):

- Heart failure
- Type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors

Inpefa was evaluated in patients with chronic kidney disease (eGFR 25 to 60 mL/min/1.73 m^2) in the SCORED study and patients with heart failure with eGFR < 60 mL/min/1.73 m^2 in the SOLOIST study. The safety profile of Inpefa across eGFR subgroups in these studies was consistent with the known safety profile and there were more hypotension and volume-depletion related adverse events in patients with an eGFR < 30 mL/min/1.73 m^2. Patients that have impaired renal function (eGFR < 60 mL/min/1.73 m^2), elderly, or patients using loop diuretics should be assessed for volume status and renal function and monitored for signs and symptoms of hypotension, and renal function after initiating therapy (1).

Inpefa is not indicated for glycemic control, but co-administration with insulin secretagogues, such as sulfonylurea medications, can increase the risk of hypoglycemia and diabetic ketoacidosis, especially in patients with Type I diabetes mellitus. Regardless of the presented blood glucose levels, if ketoacidosis is suspected, patients should stop Inpefa and achieve resolution of the condition before restarting the medication (1).

Inpefa increases the risk of genital mycotic infections and urinary tract infections. Patients should be monitored for urinary tract infections and treated promptly. Mycotic infections were more likely in patients with a history of genital mycotic infections. Appropriate treatment should be provided if an infection develops.

Safety and effectiveness of Inpefa in patients under 18 years of age have not been established (1).

Related policies
Corlanor, Verquvo

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Inpefa may be considered **medically necessary** if the conditions indicated below are met.

Inpefa may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Heart failure
2. Type 2 diabetes mellitus, chronic kidney disease, **AND** other cardiovascular risk factors

AND ALL of the following:

a. Patient has an eGFR ≥ 25 mL/min/1.73m²
b. **NO** dual therapy with other SGLT2 inhibitors (see Appendix 1)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:
1. Heart failure
2. Type 2 diabetes mellitus, chronic kidney disease, **AND** other cardiovascular risk factors

AND ALL of the following:
a. Condition has improved or stabilized on the therapy
b. **NO** dual therapy with other SGLT2 inhibitors (see Appendix 1)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Inpefa is indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure or type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors. Renal function should be monitored during SGLT2s therapy. SGLT2 Inhibitors should not be used for treatment of type 1 diabetes mellitus or diabetic ketoacidosis (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Inpefa while maintaining optimal therapeutic outcomes.

References

1. Inpefa [package insert] The Woodlands, TX: Lexicon Pharmaceuticals, Inc.; May 2023.

Policy History

Date	Action
August 2023	Addition to PA
September 2023	Annual review
March 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.

Appendix 1 - List of SGLT2 Inhibitors

Generic Name	Brand Name
canagliflozin	Invokana
canagliflozin/metformin	Invokamet/Invokamet XR
dapagliflozin	Farxiga
dapagliflozin/metformin	Xigduo XR
dapagliflozin/saxagliptin	Qtern
empagliflozin	Jardiance
empagliflozin/linagliptin	Glyxambi
empagliflozin/linagliptin/metformin	Trijardy XR
empagliflozin/metformin	Synjardy/Synjardy XR
ertugliflozin	Steglatro
ertugliflozin/metformin	Segluromet
ertugliflozin/sitagliptin	Steglujan
sotagliflozin	Inpefa