

**INPEFA
(sotagliflozin)****RATIONALE FOR INCLUSION IN PA PROGRAM****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 m²) in the SCORED study and patients with heart failure with eGFR < 60 mL/min/1.73 m² 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 m². Patients that have impaired renal function (eGFR < 60 mL/min/1.73 m²), 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



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infection develops.

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

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.; January 2024.