

# Drug Policy

<b>Policy:</b>	<b>Inpefa (sotagliflozin)</b>	<b>Annual Review Date:</b> <b>09/21/2023</b>
		<b>Last Revised Date:</b> <b>09/21/2023</b>

## 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** with<sup>1</sup>:

- 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  $\geq 18$  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  $\geq 18$  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*.*

# Drug Policy

## 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. 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

1. Inpefa™ tablets [prescribing information]. Lexicon; The Woodlands, TX: May 2023.
2. Heidenreich PA, Bozkurt B, Aguilar D et al. 2022 American Heart Association/American College of Cardiology/Heart Failure Society of America (AHA/ACC/HFSA) guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Card Fail.* 2022;28:e1-e167.
3. ElSayed NA, Aleppo G, Aroda VR. American Diabetes Association – Standards of Care in Diabetes – 2023. *Diabetes Care.* 2023;46(Suppl 1):S1-S290.
4. Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group: Rossing P, Muiza Caramori M, Chan JCN, et al. KDIGO 2022 clinical practice guideline for diabetes management in chronic kidney disease. *Kidney Int.* 2022;102(5S):S1-S127.
5. Blonde L, Umpierrez GE, Reddy SS, et al. American Association of Clinical Endocrinology clinical practice guideline: developing a diabetes mellitus comprehensive care plan – 2022 update. *Endocr Pract.* 2022;18:923-1049.
6. Boer IH, Khunti K, Sadosky T, et al. Diabetes management in chronic kidney disease: a consensus report by the American Diabetes Association (ADA) and Kidney Disease: Improving Global Outcomes (KDIGO). *Kidney International.* 2022;102:974-989.
7. Samson SL, Vellanki P, Blonde L, et al. American Association of Clinical Endocrinology consensus statement: comprehensive type 2 diabetes management algorithm – 2023 update. *Endocr Pract.* 2023;29:305-340.
8. Kittleson MM, Panjath GS, Amancherla K, et al. 2023 ACC expert consensus decision pathway on management of heart failure with preserved ejection fraction. *JACC.* 2023;81(18):1835-1878.

---

This document is subject to the disclaimer found at <https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx> and is subject to change. <https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx>

# Drug Policy

9. Davies MJ, Aroda VR, Collins BS, et al. Management of hyperglycemia in type 2 diabetes, 2022. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care*. 2022;45:2753-2786.