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IN BRIEF

Expanded Heart Failure Indication for Empagliflozin *(Jardiance)*

The sodium-glucose cotransporter 2 (SGLT2) inhibitor empagliflozin (*Jardiance* – Boehringer Ingelheim) was approved by the FDA in 2021 to reduce the risk of hospitalization for heart failure (HF) and cardiovascular death in patients with heart failure with reduced ejection fraction (HFrEF; LVEF ≤40%), regardless of whether or not they have type 2 diabetes.[1] The indication has now been expanded to include patients with HF with any ejection fraction. Empagliflozin is the first SGLT2 inhibitor to be approved in the US for this indication.

SGLT2 INHIBITORS AND HF — All currently available SGLT2 inhibitors have been shown to reduce the risk of hospitalization for HF by ~30% in patients with type 2 diabetes. The SGLT2 inhibitor dapagliflozin *(Farxiga)* was approved in 2020 to reduce the risk of hospitalization for HF and cardiovascular death in patients with HFrEF, with or without diabetes.[2] Canagliflozin *(Invokana)* and ertugliflozin *(Steglatro)*, the other two SGLT2 inhibitors available in the US, do not have a HF indication.

CLINICAL STUDIES — FDA approval for the expanded indication was based on the results of a double-blind trial (EMPEROR-Preserved) in 5988 patients with NYHA class II-IV HF and a LVEF >40% who were randomized to receive empagliflozin 10 mg or placebo once daily in addition to standard treatment for heart failure with preserved ejection fraction (HFpEF). About 50% of the patients had type 2 diabetes. Over a median follow-up of 26.2 months, the incidence of a composite of hospitalization for HF or cardiovascular death, the primary endpoint, was statistically significantly lower in the empagliflozin group than in the placebo group (13.8% vs 17.1%; 6.9 vs 8.7 events per 100 patient-years), primarily because of a lower risk of hospitalization for HF. Relative outcomes were similar in patients with or without type 2 diabetes. The number of patients needed to be treated with empagliflozin to prevent one primary outcome event was 31 (95% CI 20-69).[3]

DOSAGE AND COST — The recommended dosage of empagliflozin for all indications is 10 mg once daily. For patients with type 2 diabetes who need additional glycemic control, the dose can be increased to 25 mg. A 30-day supply of *Jardiance* costs $570.50.[4]

CONCLUSION — Addition of the sodium-glucose cotransporter 2 (SGLT2) inhibitor empagliflozin *(Jardiance)* to standard treatment for heart failure with preserved ejection fraction reduced the composite risk of hospitalization for heart failure or cardiovascular death in patients with an LVEF >40%, with or without type 2 diabetes. Empagliflozin is the first SGLT2 inhibitor to be FDA-approved for use in patients with heart failure with any ejection fraction. ■

1. Empagliflozin (Jardiance) for heart failure with reduced ejection fraction. Med Lett Drugs Ther 2021; 63:171.
2. Dapagliflozin (Farxiga) – a new indication for heart failure. Med Lett Drugs Ther 2020; 62:102.
3. SD Anker et al. Empagliflozin in heart failure with a preserved ejection fraction. N Engl J Med 2021; 385:1451.
4. Approximate WAC. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. March 5, 2022. Reprinted with permission by First Databank, Inc. All rights reserved. ©2022. www.fdbhealth.com/drug-pricing-policy.

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