Farxiga® (dapagliflozin) – New indication

- On May 5, 2020, the FDA announced the approval of AstraZeneca's Farxiga (dapagliflozin), to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (New York Heart Association [NYHA] class II-IV) with reduced ejection fraction.

- Farxiga is also approved:

  - As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM)
  - To reduce the risk of hospitalization for heart failure in adults with T2DM and established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors.
  - Farxiga is not recommended for patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

- Farxiga is the first sodium-glucose co-transporter 2 (SGLT2) inhibitor to be approved to treat adults with NYHA class II-IV heart failure with reduced ejection fraction.

- The approval of Farxiga for the new indication was based on DAPA-HF, a randomized, double-blind, placebo-controlled study in 4,744 patients with heart failure with reduced ejection fraction. The primary composite endpoint was CV death, hospitalization for heart failure or urgent heart failure visit.

  - Farxiga reduced the incidence of the primary composite endpoint with an event rate of 11.6% vs. 15.6% with placebo (hazard ratio 0.74; 95% CI: 0.65, 0.85; $p < 0.0001$).
  - All three components of the primary composite endpoint individually contributed to the treatment effect.
  - The results of the primary composite endpoint were consistent across the subgroups examined, including heart failure patients with and without T2DM.

- The recommended dose of Farxiga for the treatment of heart failure is 10 mg orally once daily.

  - Refer to the Farxiga drug label for dosing for T2DM.