Farxiga® (dapagliflozin) – New indication

- On April 30, 2021, the FDA announced the approval of AstraZeneca's Farxiga (dapagliflozin), to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease (ESKD), cardiovascular (CV) death, and hospitalization for heart failure in adults with chronic kidney disease (CKD) at risk of progression.
    - Farxiga is not recommended for the treatment of CKD in patients with polycystic kidney disease or patients requiring or with a recent history of immunosuppressive therapy for kidney disease. Farxiga is not expected to be effective in these populations.
- 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 either established CV disease or multiple CV risk factors.
    - To reduce the risk of CV death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction.
- Farxiga is the first sodium-glucose cotransporter 2 (SGLT2) inhibitor approved for the treatment of CKD regardless of diabetes status.
- The approval of Farxiga for the new indication was based on the DAPA-CKD trial, a randomized, double-blind, placebo-controlled study in 4,304 patients with CKD stages 2 to 4 and albuminuria. Patients received Farxiga or placebo, in addition to standard of care background therapy. The primary composite endpoint was worsening of renal function or risk of death (defined as a composite of an eGFR decline ≥ 50%, onset of ESKD, or death from CV or renal cause).
    - At least one composite endpoint event occurred in 197 of the 2,152 patients who received Farxiga vs. 312 of the 2,152 patients who received placebo (hazard ratio [HR] 0.61, 95% CI: 0.51, 0.72; p < 0.0001).
    - All-cause mortality occurred in 101 patients who received Farxiga vs. 146 patients who received placebo (HR 0.69, 95% CI: 0.53, 0.88; p = 0.0035).
- The recommended dose of Farxiga is based on eGFR level.

eGFR (mL/min/1.73 m^2)	Dosing frequency
eGFR 45 or greater	To improve glycemic control, the recommended starting dose is 5 mg orally once daily. Dose can be increased to 10 mg orally once daily for additional glycemic control*.

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	For all other indications, the recommended starting dose is 10 mg orally once daily.
eGFR 25 to less than 45	10 mg orally once daily*.
eGFR less than 25	Initiation is not recommended; however, patients may continue 10 mg orally once daily to reduce the risk of eGFR decline, ESKD, CV death and hospitalization for heart failure.
On dialysis	Contraindicated.

*Farxiga is not recommended for use to improve glycemic control in adults with T2DM with an eGFR less than 45 mL/min/1.73 m^2. Farxiga is likely to be ineffective in this setting based upon its mechanism of action.