Synjardy® (empagliflozin/metformin) – Expanded Indication

- On July 19, 2016, Boehringer Ingelheim announced the FDA approval of Synjardy (empagliflozin/metformin) tablets, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM) when treatment with both empagliflozin and metformin is appropriate.
    - This approval extends Synjardy use to treatment-naïve adults with T2DM.
    - Previously, Synjardy was approved in adults with T2DM who were not adequately controlled on a regimen containing empagliflozin or metformin, or in patients already being treated with both empagliflozin and metformin
- The expanded indication for Synjardy was approved based on an active-controlled study that evaluated empagliflozin in combination with metformin as initial therapy vs. the individual components.
    - At 24 weeks, the combination of empagliflozin (10 mg or 25 mg) with metformin (1,000 mg or 2,000 mg) resulted in significant reductions in average blood glucose levels compared with the corresponding dose of either component alone.
- Similar to other metformin-containing products, Synjardy carries a boxed warning regarding the risk of lactic acidosis.
- The recommended dose of Synjardy should be individualized based on the patient's current regimen. The maximum recommended oral dose is 12.5 mg empagliflozin/1,000 mg metformin twice daily.
    - Synjardy is contraindicated in patients with estimated glomerular filtration rate below 45 mL/min/1.73m^2.