Trulicity® (dulaglutide) – Expanded indication

- On November 17, 2022, the FDA approved Eli Lilly's Trulicity (dulaglutide), as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus (T2DM).
    - Trulicity was previously approved for this indication in adults only.
- Trulicity is also approved to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with T2DM who have established cardiovascular disease or multiple cardiovascular risk factors.
- The approval of Trulicity for the expanded indication was based on a 26-week randomized, double-blind, placebo-controlled study with an open-label extension for an additional 26 weeks, in 154 pediatric patients 10 years of age and older with T2DM. Patients received Trulicity (0.75 mg and 1.5 mg) or placebo, in combination with or without metformin and/or basal insulin.
    - The change in A1c from baseline at week 26 was 0.6 with placebo vs. -0.8 with Trulicity (pooled results from both dosages) (difference -1.4, 95% CI: -1.9, -0.8; $p < 0.001$).
- Trulicity carries a boxed warning for risk of thyroid C-cell tumors.
- The recommended pediatric starting dosage of Trulicity is 0.75 mg injected subcutaneously once weekly. If additional glycemic control is needed, the dosage can be increased to the maximum recommended dosage of 1.5 mg once weekly after at least 4 weeks on the 0.75 mg dosage.
    - Refer to the Trulicity drug label for dosing for its other uses.