

## Trulicity<sup>®</sup> (dulaglutide) – New indication

- On February 21, 2020, [Eli Lilly announced](#) the FDA approval of [Trulicity \(dulaglutide\)](#), to reduce the risk of major adverse cardiovascular events (MACE) (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus (T2DM) who have established cardiovascular (CV) disease or multiple CV risk factors.
  - Trulicity has not been studied in patients with a history of pancreatitis. Other antidiabetic therapies should be considered in patients with a history of pancreatitis.
  - Trulicity should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Trulicity is not a substitute for insulin.
  - Trulicity has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis. The use of Trulicity is not recommended in patients with pre-existing severe gastrointestinal disease.
- Trulicity is also approved as an adjunct to diet and exercise to improve glycemic control in adults with T2DM.
- The approval of Trulicity for the new indication was based on the REWIND study, a randomized, placebo-controlled, double-blind study in 9,901 adult patients with T2DM and established CV disease or multiple CV risk factors. Patients were randomized to Trulicity or placebo. The median follow-up duration was 5.4 years. The primary endpoint was the time to the first occurrence of a composite 3-component MACE outcome, which included CV death, non-fatal myocardial infarction, and non-fatal stroke.
  - Compared with placebo, Trulicity significantly reduced the risk of first occurrence of primary composite endpoint (12.0% vs. 13.4%; hazard ratio: 0.88; 95% CI: 0.79, 0.99; p = 0.26).
- Trulicity carries a boxed warning for risk of thyroid C-cell tumors.
- The recommended initial dose of Trulicity in all patients is 0.75 mg subcutaneously once weekly. The dose may be increased to 1.5 mg once weekly for additional glycemic control. The maximum recommended dose is 1.5 mg once weekly.
- Trulicity should be injected in the abdomen, thigh, or upper arm.