Bydureon BCise® (exenatide extended-release) – Expanded indication

- On July 23, 2021, the FDA approved AstraZeneca's Bydureon BCise (exenatide extended-release), as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus (T2DM).
    - Bydureon BCise was previously approved for this indication in adults only.
- Limitations for use for Bydureon BCise include:
    - Not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of the rat thyroid C-cell tumor findings to humans.
    - Not indicated for use in patients with type 1 diabetes mellitus.
    - Bydureon BCise is an extended-release formulation of exenatide and should not be used with other products containing the active ingredient exenatide.
    - Has not been studied in patients with a history of pancreatitis. Other antidiabetic therapies should be considered in patients with a history of pancreatitis.
- The approval of Bydureon BCise for the expanded indication was based on a 24-week, randomized, double-blind, placebo-controlled study in 82 patients age 10 to 17 years with T2DM treated with diet and exercise alone or in combination with a stable dose of oral antidiabetic agents and/or insulin. The primary endpoint was the change in HbA1c from baseline to week 24.
    - The mean change in HbA1c at week 24 was -0.25 and 0.45 for Bydureon and placebo, respectively. The difference from placebo was -0.71 (95% CI: -1.42, 0; $p < 0.05$).
- Bydureon BCise carries a boxed warning for risk of thyroid C-cell tumors.
- The recommended dose of Bydureon BCise for all patients is 2 mg subcutaneously once every 7 days (weekly). The dose can be administered at any time of day, with or without meals.