Bydureon® BCise™ (exenatide extended-release) – New formulation approval

- On October 23, 2017, AstraZeneca announced the FDA approval of Bydureon BCise (exenatide extended-release) injectable suspension as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
    - Bydureon BCise is 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.
    - Bydureon BCise is not a substitute for insulin. Bydureon BCise is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.
    - The concurrent use of Bydureon BCise with insulin has not been studied and is not recommended.
    - Bydureon BCise is an extended-release formulation of exenatide. Bydureon BCise should not be used with other products containing the active ingredient exenatide.
    - Bydureon BCise has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.

- Bydureon BCise is a new once-weekly formulation of Bydureon® injectable suspension. It is a pre-filled device with a pre-attached hidden needle. Bydureon BCise has a unique, continuous-release microsphere delivery system designed to provide consistent therapeutic levels of exenatide.
    - Bydureon is currently available as a pen and a single-dose tray formulation, both which require assembly. The Bydureon pen requires the needle to be assembled to the pen and the single dose tray requires assembly of the syringe, vial and vial connector.

- Across two clinical trials, Bydureon BCise demonstrated average hemoglobin $A1_c$ reductions of up to 1.4% and average weight loss of up to 3.1 pounds when used as monotherapy or as an add-on to metformin, a sulfonylurea, a thiazolidinedione, or any combination of two of these oral anti-diabetic medicines at 28 weeks.

- Bydureon BCise carries the same *Boxed Warning*, *Contraindications*, and *Warnings and Precautions* sections as Bydureon.

- Bydureon BCise carries a boxed warning for risk of thyroid c-cell tumors.

- Bydureon BCise is contraindicated in patients with a personal of family history of medullary thyroid carcinoma or in patients with multiple endocrine neoplasia syndrome type 2, and in patients with a prior hypersensitivity reaction to exenatide or to any components of Bydureon BCise.

- Other warnings and precautions of Bydureon BCise include acute pancreatitis, hypoglycemia with concomitant use of insulin secretagogues or insulin, acute injury and impairment of renal function, gastrointestinal disease, immunogenicity, injection site reactions, and macrovascular outcomes.

- The most common adverse events (≥ 5%) with Bydureon BCise use were injection site nodule and nausea.

- Similar to Bydureon, the recommended dose of Bydureon BCise is 2 mg administered subcutaneously once every 7 days. The dose can be administered at any time of day, with or without meals.

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  - — Prior treatment with an immediate- (IR) or extended-release (ER) exenatide product is not required when initiating Bydureon BCise therapy. Discontinue any IR or ER exenatide product prior to initiation of Bydureon BCise.
  - — Patients changing from IR exenatide to Bydureon BCise may experience transient (approximately 2 to 4 weeks) elevations in blood glucose concentrations.
  - — Patients changing from another ER exenatide product to Bydureon BCise may do so at the next regularly scheduled dose.

- AstraZeneca plans to launch Bydureon BCise in the first quarter of 2018. It will be available as a pre-filled disposable single dose autoinjector containing 2 mg of exenatide per 0.85 mL of suspension. Bydureon Pen will remain available