Supplemental Approvals

Generic Name (Trade Nameâ€"Company)

Uses/Notes

April 4, 2018

Exenatide extended-release

(Bydureon—AstraZeneca)

Approval of exenatide ER expanded for use with basal insulin to treat uncontrolled T2D

FDA has approved exenatide extended-release (ER) for injectable suspension as add-on therapy to basal insulin in adults with type 2 diabetes (T2D) with inadequate glycemic control despite taking one or more antidiabetic medications and making diet and exercise changes.

The expanded use is based on results from the 28-week DURATION-7 study, which examined the effect of exenatide ER or placebo as add-on therapy to insulin glargine, with or without metformin, in adults with T2D. Mean A1C was reduced by 0.9% in the exenatide extended-release group compared to 0.2% in the placebo group in patients with a mean baseline A1C of 8.5%.

Furthermore, 32.5% of patients in the exenatide extended-release group reached an A1C of less than 7.0% compared to 7.0% of patients in the placebo group.

No new safety data were found in the DURATION-7 study. Overall hypoglycemia was similar between the groups, with no reported major hypoglycemia. In both arms, the same percentage of patients reported minor hypoglycemia.

Like other GLP-1 receptor agonists, the risk of hypoglycemia is increased when exenatide extended-release is coadministered with insulin. Prescribers should consider lowering the dose of insulin when coadministering exenatide extended-release.

The most common adverse events are nausea, diarrhea, headache, vomiting, constipation, injection-site pruritus, injection-site nodule, and dyspepsia.

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