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IN BRIEF

Empagliflozin (*Jardiance*) for Type 2 Diabetes in Children

The sodium-glucose cotransporter 2 (SGLT2) inhibitor empagliflozin has been available for years alone (*Jardiance* – Boehringer Ingelheim) and in combination with metformin (*Synjardy*) to improve glycemic control in adults with type 2 diabetes. Both products have now been approved for use in children ≥10 years old. Empagliflozin is the second oral drug to become available in the US for treatment of type 2 diabetes in children; metformin has been available since 2000 for this indication. The injectable glucagon-like peptide-1 (GLP-1) receptor agonists liraglutide (*Victoza*) and extended-release exenatide (*Bydureon BCise*) are also approved for use in children ≥10 years old.¹

MECHANISM OF ACTION – SGLT2 inhibitors decrease renal glucose reabsorption and increase urinary glucose excretion, reducing fasting and postprandial blood glucose levels.

CLINICAL STUDIES – FDA approval of the expanded indication was based on the results of a double-blind trial (DINAMO) in 158 patients 10-17 years old with an A1C of 6.5-10.5% who were randomized to receive empagliflozin, the dipeptidyl peptidase-4 (DPP-4) inhibitor linagliptin (off-label), or placebo once daily. Most patients in the trial were also taking metformin and/or insulin. At week 26, the mean change from baseline in A1C was -0.17% with empagliflozin, +0.33% with linagliptin, and +0.68% with placebo; the difference between empagliflozin and placebo was statistically significant. Compared to placebo, there was a mean weight loss of 0.75 kg with empagliflozin and a weight gain of 1.46 kg with linagliptin.²

ADVERSE EFFECTS – Adverse effects of SGLT2 inhibitors include genital mycotic infections, urinary tract infections, and volume depletion, which can lead to hypotension and acute kidney injury. Empagliflozin has been associated with ketoacidosis in patients with type 1 diabetes and in some insulin-deficient patients with type 2 diabetes.

DOSAGE, ADMINISTRATION, AND COST – *Jardiance* is available in 10- and 25-mg tablets. The recommended starting dosage for treatment of type 2 diabetes in patients of any age is 10 mg once daily; the dose can be increased to 25 mg as needed. *Synjardy*, which is available in tablets containing 5 or 12.5 mg of empagliflozin and either 500 or 1000 mg of metformin, is taken twice daily. The maximum daily dose is 25 mg/2000 mg. The wholesale acquisition cost for a 30-day supply of *Jardiance* or *Synjardy* is \$593.30.³

CONCLUSION – Addition of the oral SGLT2 inhibitor empagliflozin (*Jardiance*) to metformin and/or insulin reduced A1C in one small trial in patients 10-17 years old with type 2 diabetes. ■

1. Drugs for type 2 diabetes. *Med Lett Drugs Ther* 2022; 64:177.
2. LM Laffel et al. Efficacy and safety of the SGLT2 inhibitor empagliflozin versus placebo and the DPP-4 inhibitor linagliptin versus placebo in young people with type 2 diabetes (DINAMO): a multicentre, randomised, double-blind, parallel group, phase 3 trial. *Lancet Diabetes Endocrinol* 2023; 11:169.
3. Approximate WAC for 30 days' treatment with the usual dosage. WAC=wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. July 5, 2023. Reprinted with permission by First Databank, Inc. All rights reserved. ©2023. www.fdbhealth.com/policies/drug-pricing-policy.

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