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IN BRIEF

Semaglutide (*Wegovy*) for Weight Loss in Children

The injectable glucagon-like peptide-1 (GLP-1) receptor agonist semaglutide (*Wegovy*), which was approved by the FDA in 2021 for chronic weight management in adults,¹ has now been approved for chronic weight management in children ≥ 12 years old with an initial BMI in the ≥ 95 th percentile for age and sex. Semaglutide is also available as *Ozempic* and *Rybelsus* for treatment of type 2 diabetes in adults.²

GUIDELINES — Recently published guidelines from the American Academy of Pediatrics recommend that weight loss pharmacotherapy be offered in addition to lifestyle modification (e.g., nutritional counseling, exercise) to children ≥ 12 years old with obesity (BMI in the ≥ 95 th percentile) and may be offered to those 8-11 years old.³

PHARMACOTHERAPY — The injectable GLP-1 receptor agonist liraglutide (*Saxenda*), the lipase inhibitor orlistat (*Xenical*), and the combination of phentermine and topiramate (*Qsymia*) are FDA-approved for weight management in children ≥ 12 years old.^{4,5} Metformin and the GLP-1 receptor agonist exenatide (*Bydureon BCise*) are FDA-approved for treatment of type 2 diabetes in patients ≥ 10 years old and have produced modest weight loss.²

CLINICAL STUDIES — FDA approval of *Wegovy* for the new indication was based on the results of a double-blind trial (STEP TEENS) in 201 patients 12-17 years old with a BMI in the ≥ 95 th percentile (obese) or in the ≥ 85 th percentile (overweight) with ≥ 1 weight-related comorbidity. Patients were randomized to receive semaglutide 2.4 mg or placebo SC once weekly for 68 weeks, in addition to lifestyle intervention. The mean percentage change in BMI from baseline to week 68 was statistically significantly greater with semaglutide than with placebo (-16.1% vs +0.6%). At week 68, 73% of patients in the semaglutide group and 18% of those in the placebo group had $\geq 5\%$ weight loss. Improvements in cardiometabolic risk

factors, such as A1C and low-density lipoprotein cholesterol (LDL-C) levels, were also greater with semaglutide.⁶

No trials directly comparing semaglutide (*Wegovy*) with liraglutide (*Saxenda*) for weight loss in children are available. In one 68-week clinical trial (STEP-8) comparing the two drugs in adults with obesity, mean weight loss from baseline was significantly greater with once-weekly semaglutide than with once-daily liraglutide (-15.8% vs -6.4%), and treatment discontinuation occurred less often with semaglutide.⁷

ADVERSE EFFECTS — In STEP TEENS, GI adverse effects were the most common adverse effects of semaglutide (62% vs 42% with placebo), but they were generally mild to moderate in severity. Cholelithiasis was reported in 4% of semaglutide-treated children in the trial. Hypoglycemia (rarely with monotherapy), acute pancreatitis, acute kidney injury, injection-site reactions, serious hypersensitivity reactions, and increases in heart rate can occur. Suicidal ideation and behavior have been observed with other weight management products, including liraglutide. Worsening of diabetic retinopathy (associated with large reductions in blood glucose levels) has occurred with use of SC semaglutide in patients with type 2 diabetes.

As with other GLP-1 receptor agonists, the label of semaglutide includes a boxed warning about a risk of thyroid C-cell tumors (based on animal data; no corroborating human data). The drug is contraindicated in patients with a personal or family history of medullary thyroid carcinoma and in those with multiple endocrine neoplasia syndrome type 2.

DRUG INTERACTIONS — GLP-1 receptor agonists slow gastric emptying and can delay the absorption of oral drugs in the small intestine.

DOSAGE, ADMINISTRATION, AND COST — The recommended starting dosage of *Wegovy* for weight management in patients ≥ 12 years old is 0.25 mg

injected subcutaneously in the abdomen, thigh, or upper arm once weekly. After the first 4 weeks, the dose should be titrated at 4-week intervals to 0.5 mg, 1 mg, 1.7 mg, and 2.4 mg (maintenance dose). In children who cannot tolerate the 2.4-mg dose, the dosage should be reduced to 1.7 mg weekly; the drug should be stopped if the 1.7-mg dose is not tolerated. Cessation of treatment can lead to weight regain. A 28-day supply of Wegovy costs \$1349.⁸ ■

1. Semaglutide (Wegovy) for weight loss. *Med Lett Drugs Ther* 2021; 63:106.
2. Drugs for type 2 diabetes. *Med Lett Drugs Ther* 2022; 64:177.
3. SE Hampl et al. Clinical practice guideline for the evaluation and treatment of children and adolescents with obesity. *Pediatrics* 2023 Jan 9 (epub).
4. Liraglutide (Saxenda) for weight loss. *Med Lett Drugs Ther* 2015; 57:89.
5. Drugs and devices for weight management. *Med Lett Drugs Ther* 2022; 64:81.
6. D Weghuber et al. Once-weekly semaglutide in adolescents with obesity. *N Engl J Med* 2022; 387:2245.
7. DM Rubino et al. Effect of weekly subcutaneous semaglutide vs daily liraglutide on body weight in adults with overweight or obesity without diabetes: the STEP 8 randomized clinical trial. *JAMA* 2022; 327:138.
8. Approximate WAC for the recommended maintenance 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. January 5, 2023. Reprinted with permission by First Databank, Inc. All rights reserved. ©2023. www.fdbhealth.com/drug-pricing-policy.

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