

Wegovy[®] (semaglutide) – Expanded indication

- On December 23, 2022, [Novo Nordisk announced the FDA approval of Wegovy \(semaglutide\)](#), for chronic weight management in pediatric patients aged 12 years and older with an initial body mass index (BMI) at the 95th percentile or greater for age and sex (obesity).
 - Wegovy was previously approved in adult patients only as outlined below.
- Wegovy is also approved for chronic weight management in adults with an initial BMI of 30 kg/m² or greater (obesity) or a BMI 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (eg, hypertension, type 2 diabetes mellitus, or dyslipidemia).
- The approval of Wegovy for the expanded indication was based on a 68-week, double-blind, randomized, parallel group, placebo-controlled study of 201 pubertal pediatric patients aged 12 years and older with BMI corresponding to ≥ 95th percentile standardized for age and sex. Patients received Wegovy or placebo once weekly. The primary endpoint was percent change in BMI from baseline to week 68.
 - At week 68, the least squares mean change in BMI was -16.1% for Wegovy-treated patients vs. 0.6% for placebo-treated patients (treatment difference -16.7%; 95% CI: -20.3, -13.2; p < 0.0001).
- Wegovy carries a boxed warning for risk of thyroid C-cell tumors.
- The recommended initial dose of Wegovy for the treatment of adults and pediatric patients 12 years of age and older is a dosage of 0.25 mg injected subcutaneously (SC) once weekly. Then follow the dose escalation schedule outlined in the drug label to minimize gastrointestinal adverse reactions.
 - In pediatric patients, the recommended maintenance dosage of Wegovy is 2.4 mg injected SC once weekly. If patients do not tolerate the maintenance 2.4 mg once-weekly dosage, the maintenance dosage may be reduced to 1.7 mg once weekly. Wegovy should be discontinued if the patient cannot tolerate the 1.7 mg dose.
 - Refer to the Wegovy drug label for further information about adult and pediatric dosing for all its indications.