CLOSER LOOK

MEMORANDUM

FDA approves Novo Nordisk's high-dose Wegovy (semaglutide 7.2 mg) for adults with obesity – March 19, 2026

Approval based on the phase 3b STEP UP trial (n=1,407), where semaglutide 7.2 mg conferred 20.7% weight loss at Week 72; commercial launch expected in April 2026

The FDA announced today that it has approved a higher dose of Novo Nordisk's Wegovy injection (semaglutide 7.2mg), "Wegovy HD," under the Commissioner's National Priority Voucher (CNPV) pilot program. The approval, granted 54 days after filing, includes adults with obesity (BMI ≥30 kg/m^2) who have already tolerated semaglutide 2.4 mg for at least four weeks and for whom additional weight reduction is clinically indicated.

If all goes as planned, Wegovy will soon be available in six once-weekly doses: (i) 0.25 mg; (ii) 0.5 mg; (iii) 1 mg; (iv) 1.7 mg; (v) 2.4 mg; and (vi) 7.2 mg. Additionally, there will be availability for a once-daily oral pill of Wegovy (semaglutide 1.5 mg), which received approval in December 2025. While we think the choices are an embarrassment of riches of sorts, this is also a lot for the average clinician to keep track of.

Novo Nordisk expects to launch Wegovy HD in April 2026 for patients in the US – pretty fast!

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Semaglutide 7.2 mg demonstrated 20.7% weight loss in the phase 3b STEP UP trial

The approval was based on results from the phase 3b STEP UP trial (n=1,407), which compared semaglutide 7.2 mg against semaglutide 2.4 mg (previously the highest dose of Wegovy) and placebo in adults with overweight and obesity. The trial met its primary endpoint, with semaglutide 7.2 mg demonstrating a statistically significant and superior weight loss of 20.7% at Week 72 compared with semaglutide 2.4 mg and placebo.

At Week 72, semaglutide 7.2 mg conferred 20.7% weight loss from a mean baseline weight of 113 kg (249 lbs), compared to 17.5% with semaglutide 2.4 mg and 2.4% with placebo. Moreover, 33% of people treated with semaglutide 7.2 mg achieved a weight loss of ≥25%, compared to 17% with semaglutide 2.4 mg and none with placebo. When applying the treatment policy estimand, people treated with semaglutide 7.2 mg achieved weight loss of 18.7%, compared to 15.6% with semaglutide 2.4 mg and 3.9% with placebo.

On safety, semaglutide 7.2 mg had a safe and well-tolerated profile. Most adverse events were GI-related, with the majority being mild-to-moderate and diminishing over time.

Full results from the STEP UP trial will be presented at an undisclosed conference in 2026. Novo Nordisk is also studying semaglutide 7.2 mg in the phase 3 STEP UP T2D trial (n=512) in adults with T2D and obesity.

Commissioner's National Priority Voucher Program offers accelerated review of drug applications

As explained in the FDA's October 2025 program announcement, CNVP convenes a team of physicians and scientists to engage in team-based, rolling review of company submissions to the FDA, interacting frequently with the companies to clarify questions and complete application review. After these streamlined review steps are complete, the team convenes

for a one-day “tumor board style” meeting to determine approval. FDA reserves the right to extend the review time if the application is deemed incomplete.

The approval of Wegovy HD marks the fourth under the FDA’s CNVP program.

Tirzepatide and combination treatments confer similar weight loss as high-dose semaglutide

In December 2024, Novo Nordisk announced topline results from the phase 3 REDEFINE 1 trial (n=3,417) of CagriSema (fixed dose combination of cagrilintide 2.4 mg and semaglutide 2.4 mg) in people with overweight or obesity. At Week 68, CagriSema reduced weight loss by 20.4%, compared 11.5% with cagrilintide 2.4 mg, 14.9% with semaglutide 2.4 mg, and 3.0% with placebo.

In the phase 3b SURMOUNT-5 (n=700) trial, tirzepatide conferred a superior weight loss of 20.2% compared to 13.7% by semaglutide at Week 72. In the phase 3 SURMOUNT-1 trial (n=1,032), tirzepatide demonstrated weight loss of up to 22.5%, compared to 2% with placebo, at Week 173.

Close Concerns’ Questions with Answers from Novo Nordisk

Q: Are there any intermediary semaglutide doses between 2.4 mg and 7.2 mg that patients might use to improve tolerability?

A: Patients have to be on 2.4mg for at least four weeks before titrating to 7.2mg. There are no intermediate doses between 2.4mg and 7.2mg. Per the STEP UP trial, Gastrointestinal and dysaesthesia adverse events were more common with the 7・2 mg dose than with 2・4 mg and placebo; most were mild to moderate in severity. Specifically - dysaesthesia adverse events were mild for most participants who experienced them (177 in the semaglutide 7・2 mg group, nine in the semaglutide 2・4 mg group, and one in the placebo group), and there were no serious events. Serious adverse events were reported by 68 (6·8%) of 1004 participants with semaglutide 7·2 mg, 22 (10·9%) of 201 with semaglutide 2·4 mg, and 11 (5·5%) of 201 with placebo.

Q: How might Wegovy HD be differentiated from tirzepatide or combination treatments?

A: We cannot speak to other treatments in which Wegovy 7.2mg has not been directly studied against.

Q: Will Novo Nordisk pursue creating an oral pill of high-dose semaglutide?

A: As you may know, the highest dose of the Wegovy pill is 25mg. We do not have anything to share further.

-- by Elizabeth Rose, Kat Moon, Monica Oxenreiter, and Kelly Close