CLOSER LOOK

MEMORANDUM

EU's CHMP issues a positive opinion of higher dose Wegovy (semaglutide 7.2 mg) to expand treatment for people with obesity by early 2026 – December 12, 2025

Follows last month's supplemental New Drug Application (sNDA) submission to the FDA for Wegovy (semaglutide 7.2 mg) for obesity in the US

Novo Nordisk announced today that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion for a higher dose of Wegovy (semaglutide 7.2 mg), positioning it for potential EU approval early next year. The positive opinion is supported by the results of the phase 3b STEP UP trial (n=1,407), which evaluated high-dose semaglutide in people with overweight or obesity and without T2D.

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Parallels regulatory momentum in the US

Today's news follows Novo Nordisk's submission of a supplemental New Drug Application (sNDA) to the FDA last month. In the US, Wegovy is one of 15 candidates that received the new Commissioner's National Priority voucher (CNPV), which would allow for an expedited review within one or two months after the FDA accepts the application. In the EU, Novo Nordisk expects that the higher semaglutide dose could be available as early as 2026 for people with obesity.

Higher dose semaglutide drives greater weight loss in people with obesity and without T2D in phase 3 STEP UP trial

The EMA's positive opinion is supported by results from the phase 3b STEP UP trial (n=1,407), which evaluated semaglutide 7.2 mg in people with overweight or obesity without T2D. Full results presented at ADA 2025 showed that at 72 weeks, participants achieved an average weight loss of 20.7%, compared to 17.5% with the 2.4 mg dose and 2.4% with placebo. One-third of those on the 7.2 mg dose reached ≥25% weight loss, and body composition analysis confirmed that the majority of the weight lost was fat mass, suggesting some preservation of muscle function. These data suggest that dose escalation may offer additional weight loss potential for individuals who do not respond optimally to lower doses.

Tolerability considerations with 7.2 mg semaglutide

While a higher dose of semaglutide appears to offer greater efficacy, tolerability remains a key consideration. In the STEP UP trial, GI side effects were more frequent with the 7.2 mg dose (71%) compared to 2.4 mg (61%) and placebo (43%), and fewer participants reached the maximum dose (75% vs. 89% for 2.4 mg). While discontinuation rates were low across all groups, the higher incidence of GI events likely reflects real-world adherence and patient selection.

Close Concerns' Questions

1. Who will be prioritized for the higher 7.2 mg dose – those not achieving sufficient weight loss on 2.4 mg, and/or individuals with specific obesity-related complications?

2. How will clinicians determine appropriate escalation to 7.2 mg, and what guidelines will be needed to standardize practice across the EU and globally?
3. How will payers and health systems ensure that those who most need the higher dose, such as people with severe obesity or high cardiometabolic risk, can access it?

--by Kayla Mathieu, Esther Min, Monica Oxenreiter, and Kelly Close