CLOSER LOOK

MEMORANDUM

Lilly's oral GLP-1 RA Foundayo (orforglipron) receives FDA approval for weight loss – April 1, 2026

Approval based on ATTAIN-1 trial, in which orforglipron achieved 12.4% weight loss at 72 weeks

Lilly announced today that the FDA approved Foundayo (orforglipron), a once-daily oral GLP-1 RA for weight loss in adults with obesity or overweight and weight-related comorbidities. The therapy can be taken at any time of day without food or water restrictions. The drug was approved under the FDA Commissioner's National Priority Voucher (CNPV) pilot program.

Foundayo will be available immediately through LillyDirect, with broader US pharmacy availability beginning shortly after. This is consistent with previous reports, in which Lilly indicated orforglipron would be shipped within a week of approval.

Table of Contents

1. ATTAIN-1 trial demonstrated significant weight loss in people with overweight or obesity
2. Approved dosages are smaller than those investigated in the ATTAIN-1 trial
3. Oral GLP-1 RA market continues to expand, beginning with oral Wegovy's January launch
4. Orforglipron to be priced at $149/month for self-pay patients
5. Close Concerns' Questions

ATTAIN-1 trial demonstrated significant weight loss in people with overweight or obesity

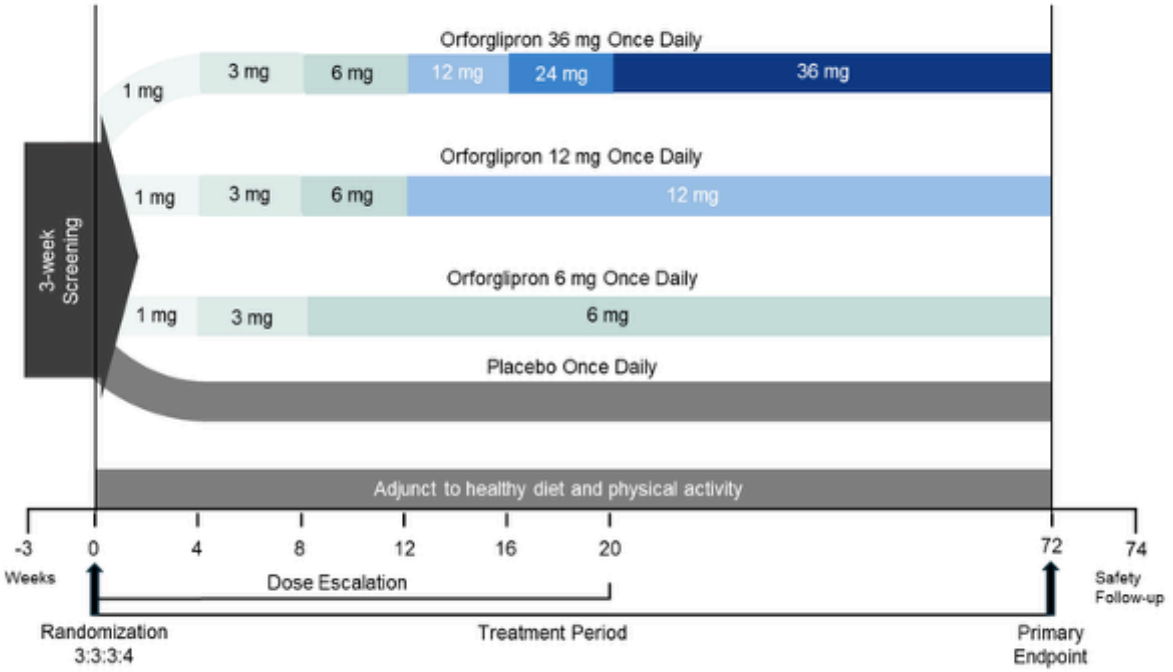
Foundayo's approval is supported by the ATTAIN clinical program, including the ATTAIN-1 trial (n=3,127), where adults on the highest dose of orforglipron saw an average of 12.4% weight loss (27.2 lbs) compared with 0.9% (2.2 lbs) on placebo. Interestingly, the approved doses are 0.8 mg, 2.5 mg, 5.5 mg, 9 mg, 14.5 mg, or 17.2 mg, which are different from the doses investigated in the ATTAIN-1 trial (6 mg, 12 mg, and 36 mg).

When including all participants, including dropouts, weight loss averaged 11.1% (25 lbs) versus 2.1% (5.3 lbs) with placebo. At the highest dose, approximately 60% of participants achieved body weight reduction of ≥10%. Moreover, 40% of participants achieved body weight reduction of ≥15%. The program also demonstrated improvements in waist circumference, non-HDL cholesterol, triglycerides, and systolic blood pressure. The safety of orforglipron was consistent with the overall profile of the GLP-1 RA class.

Approved dosages are smaller than those investigated in the ATTAIN-1 trial

As shown in the figure below, the starting study dose was 1 mg, which was escalated every four weeks to the target dosages of 6 mg, 12 mg, and 36 mg. Intermediary dosages were 3 mg, 6 mg, 12 mg, and 24 mg.

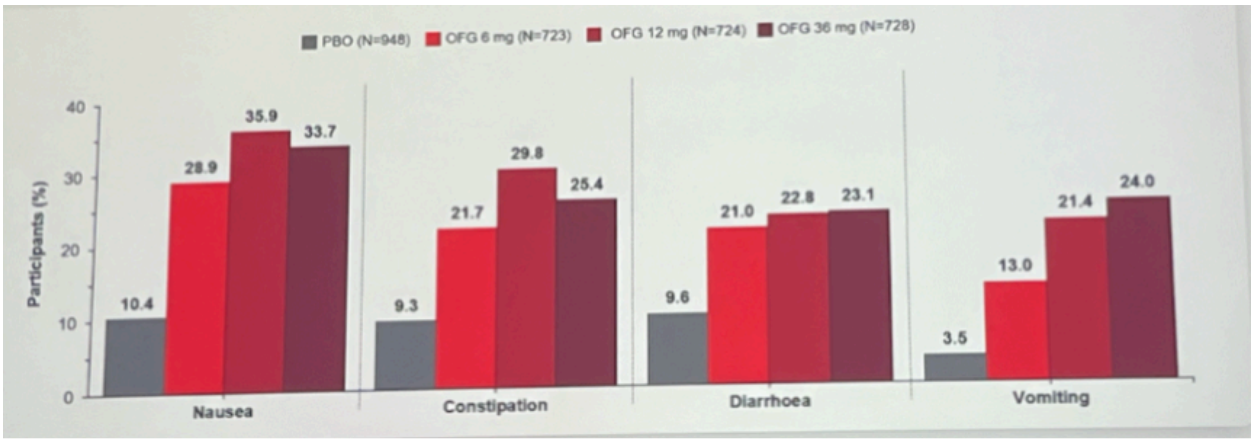
Figure 1. Titration schedule in the ATTAIN-1 trial



Source: Orforglipron, an Oral Small-Molecule GLP-1 Receptor Agonist for Obesity Treatment, *NEJM* 2025

This titration scheme significantly differs from the dosages approved by the FDA: 0.8 mg, 2.5 mg, 5.5 mg, 9 mg, 14.5 mg, or 17.2 mg. Neither Lilly nor the FDA explained the difference between the study scheme and the label dosage. In the ATTAIN-1 trial, 29-36% of participants experienced nausea (vs. 10% with placebo), 22-30% experienced constipation (vs. 9%), 21-23% reported diarrhea (vs. 10%), and 13-24% noted vomiting (vs. 4%). Moreover, discontinuations due to GI events were greater in number with higher doses: 10%, 8%, 5%, and 3% for orforglipron 36 mg, 12 mg, and 6 mg, respectively.

Figure 2. Gastrointestinal adverse events of orforglipron



Source: ATTAIN-1 trial readout at EASD 2025

Oral GLP-1 RA market continues to expand, beginning with oral Wegovy's January launch

Novo Nordisk's oral Wegovy launched in January 2026 and has already demonstrated exceptional uptake following its December 2025 FDA approval, reaching roughly 50,000 weekly prescriptions by January 23, with ~45,000 coming through the self-pay channel.

Several other companies are also advancing early-stage oral incretin programs. Viking's oral VK2735, a dual GLP-1/GIP RA, produced 8.3% weight loss at 13 weeks in its phase 2 VENTURE-Oral trial (n=280), with regulatory discussions planned for late 2025. In addition, AstraZeneca continues to progress AZD5004 through two phase 2b studies in obesity and T2D.

Orforglipron to be priced at $149/month for self-pay patients

Commercially insured patients may pay as little as $25 per month with a savings card. Self-pay pricing starts at $149 per month for the lowest dose, which is the same as the starting dose of Novo Nordisk's oral Wegovy. Medicare Part D beneficiaries may access Foundayo for $50 per month beginning July 1, 2026.

Close Concerns' Questions

1. How will providers differentiate between Foundayo and oral Wegovy when consulting patients on expected weight loss and tolerability?
2. How will payers evaluate Foundayo's clinical profile relative to injectable GLP-1 RAs when determining step-therapy requirements?
3. Will Foundayo be labeled to be interchangeable with injected GLP-1 RAs?

-- by Kayla Mathieu, Kat Moon, Monica Oxenreiter, and Kelly Close