Optum Rx®

Pipeline insights summary

Drugs to watch.

Injectible

Zepbound™ (tirzepatide)
FDA approval November 8, 2023

Tirzepatide belongs to a class of chronic weight management drugs called glucagon-like peptide 1 (GLP-1) agonists. GLP-1 drugs mimic the action of a hormone involved in regulating appetite and caloric intake. Historically, anti-obesity medications often showed poor efficacy, as well as a dubious safety record.

GLP-1 receptor agonists have become the most-used drugs for chronic weight management. Tirzepatide will compete with two existing GLP-1 options, Saxenda® and Wegovy®. The main differentiator for tirzepatide is that it provides larger reductions in body weight.

Unlike existing competitors, tirzepatide does not yet have cardiovascular outcomes data. Phase 3 cardiovascular outcomes data is expected in 2024. New competitors may also arise in 2024.

For reference, the Wholesale Acquisition Cost (WAC) for Wegovy is approximately $17,500 per year.

Infused

Donanemab: Brand name: TBD
Expected FDA decision: March 2024

Donanemab, made by Eli Lilly, is intended to treat mild cognitive impairment due to Alzheimer's disease.

Alzheimer's disease is an irreversible, progressive brain disorder that slowly destroys memory and cognition. It affects about 6.5 million people in the U.S. and is the fifth leading cause of death among adults aged 65 years or older.

Donanemab is an anti-amyloid drug that functions by removing the amyloid plaques that are believed to damage and destroy neurons.

In trials, donanemab showed comparable efficacy to Leqembi®, the only anti-amyloid therapy fully approved by the U.S. Food and Drug Administration (FDA).

While donanemab did statistically reduce decline progression, the benefit may not be clinically meaningful. Both Leqembi and donanemab exhibited side effects in the brain, including hemorrhage.

For reference, the WAC for Leqembi is approximately $26,500 per year.

Exagamglogene autotemcel: Brand name: TBD
Expected FDA decision: December 8, 2023

Exagamglogene autotemcel (exa-cel), by Vertex Pharmaceuticals/CRISPR Therapeutics, is a gene-editing therapy. It aims to treat severe sickle cell disease and transfusion-dependent beta thalassemia.

Historically, the only cure for both severe sickle cell disease and transfusion-dependent beta thalassemia was bone marrow (stem cell) transplantation. However, few people qualify since matching donors are very rare.

Since it permanently corrects faulty genes, exa-cel would be a one-time treatment and an alternative to stem cell transplant.

The short-term efficacy data for exa-cel are promising. No secondary malignancies have been reported.

However, only a small subset of patients would be eligible for treatment based on clinical criteria. Also, long-term durability of response and safety are unknown.

For reference, the WAC for Zynteglo is $2.8 million for a one-time dose.

Lovotibeglogene autotemcel: Brand name: TBD
Expected FDA decision: December 20, 2023

Lovotibeglogene autotemcel (lovo-cel) from bluebird bio is a gene therapy for severe sickle cell disease. Lovo-cel delivers functional copies of the gene responsible for severe sickle cell disease directly into a patient's bone marrow.

Lovo-cel would be a potential competitor to exa-cel (see above) and another alternative to stem cell transplantation. Like exa-cel, lovo-cel would be a one-time treatment. Trial efficacy data for lovo-cel are promising, but with the same uncertainties (i.e. long term durability of response).

Lovo-cel presents an increased risk of blood cancers, similar to Zynteglo.

For reference, the WAC for Zynteglo is $2.8 million for a one-time dose.

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