Anti-Obesity Drugs: Patents and Pipeline

KEI Briefing Note 2024:1
January 2024

Arianna Schouten
Knowledge Ecology International

Table of Contents

Background **2**
Existing Weight Loss Drugs *2*
Table 1: FDA-approved drugs indicated for long-term weight management 3
Off-label use of anti-obesity drugs *4*
Table 2: Off-Label Anti-Obesity Medicines 5
Rare genetic conditions causing obesity *5*
Table 3: Orphan Drug Anti-Obesity 6
Cardiovascular Outcomes *6*
Patent Landscape of Anti-Obesity GLP-1 Drugs **7**
Method *7*
Semaglutide Patent Landscape *7*
Table 4. Semaglutide Patents 7
Patent Dispute *11*
Drug Shortage and Compounding *11*
Generica Semaglutide *12*
Liraglutide Patent Landscape *12*
Table 5. Liraglutide patents 12
Generic Liraglutide *14*
Overlapping Patents for Liraglutide and Semaglutide *15*
Tirzepatide Patent Landscape *15*
Table 6. Tirzepatide patents 15
Drug Shortage *15*
Pipeline of Anti-Obesity Drugs **16**
Anti-Obesity Drugs in the Pipeline *16*
Table 7. Anti-Obesity Drug Pipeline 16
Figure 1: Frequency of drug classes in the anti-obesity pipeline 21

Background

Existing Weight Loss Drugs

In the early 2020s, new GLP-1 agonists became the newest popular weight loss drug due to how effective they were compared to earlier drugs. Before this, the FDA had approved treatments for obesity that had an average placebo-adjusted weight reduction in the single digits.[1] As greater weight loss was achieved with previous weight loss medications (greater than 10%), it was typically accompanied by various acute and chronic adverse effects. Semaglutide, and broadly GLP-1 agonists, provide a notable exception to this.

Currently approved GLP-1 agonists for chronic weight management are tirzepatide, semaglutide and liraglutide. The former two demonstrate placebo-adjusted weight loss exceeding 10%. These medications have gained approval from the FDA for adults with obesity or who are overweight with at least one weight-related health condition (such as high blood pressure or type 2 diabetes). Given that approximately 70% of American adults have obesity or are overweight, there are many public health arguments for the justification of the medication's use. Although, all FDA-approved anti-obesity medications are explicitly indicated as adjunctive therapies to be used in conjunction with diet and exercise.

Table 1, presented below, provides a comprehensive overview of FDA-approved medications for chronic weight management, showcasing various classes of drugs and their respective approval details. The medications in the table belong to different drug classes, including incretin mimetics, anorexants, and peripherally acting antiobesity agents. Notably, the more recently approved GLP-1 agonists, namely Semaglutide (Wegovy) and Tirzepatide (Zepbound), demonstrate the highest levels of efficacy with placebo-adjusted weight losses of 12.4% and 21.4%, respectively. Goldman Sachs has indicated that the recently approved Zepbound, a dual hormone incretin mimetic, is expected to be the "future market leader".[2]

---

[1] Müller, T.D., Blüher, M., Tschöp, M.H. and DiMarchi, R.D., 2022. Anti-obesity drug discovery: advances and challenges. *Nature Reviews Drug Discovery*, *21*(3), pp.201-223, https://www.nature.com/articles/s41573-021-00337-8 and American Diabetes Association, 2020. 8. Obesity management for the treatment of type 2 diabetes: Standards of Medical Care in Diabetes—2020. *Diabetes Care*, *43*(Supplement_1), pp.S89-S97.

[2] Madison Muller, How a Lucky Break Fueled Eli Lilly's $600 Billion Weight-Loss Empire, 26 January 2024. https://www.bloomberg.com/news/features/2024-01-26/zepbound-how-eli-lilly-s-lucky-break-fueled-a-600b-weight-loss-empire

Table 1: FDA-approved drugs indicated for long-term weight management

Active Ingredient (Brand Name)	Drug Class	Approval Date (dd/mm/yyyy) & Status /Review	Approval Indication(s)	Placebo-adjusted weight loss
Semaglutide (Wegovy) Novo Nordisk	Incretin Mimetic	FDA 06/04/2021 Priority Review Status	Indicated as an adjunct to a reduced calorie diet and increasing physical activity for chronic weight management.	12.4%[3]
Tirzepatide (Zepbound) Eli Lilly	Incretin Mimetic	FDA 11/08/2023 Priority Review Status	Indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults. Making official the off-label use of Tirzepatide which was approved for diabetes with the name Mounjaro.	21.4%[4]
Naltrexone-bupropion (Contrave)	Anorexiant	FDA 09/10/2014	Indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults	2.4 - 3.2%[5]
Liraglutide (Saxenda)	Incretin Mimetic	FDA 12/23/2014	Indicated as an adjunct to reduced-calorie diet and increased physical activity for chronic weight management in adult patients	5.4%[6]

[3] Wilding, J.P., Batterham, R.L., Calanna, S., Davies, M., Van Gaal, L.F., Lingvay, I., McGowan, B.M., Rosenstock, J., Tran, M.T., Wadden, T.A. and Wharton, S., 2021. Once-weekly semaglutide in adults with overweight or obesity. *New England Journal of Medicine, 384*(11), pp.989-1002. https://www.nejm.org/doi/full/10.1056/NEJMoa2032183

[4] Tirzepatide demonstrated significant and superior weight loss compared to placebo in two pivotal studies, July 27, 2023. https://investor.lilly.com/news-releases/news-release-details/tirzepatide-demonstrated-significant-and-superior-weight-loss#:~:text=sustained%20weight%20loss.-,For%20the%20efficacy%20estimand%2C%20those%20taking%20tirzepatide%2C%20on%20average%2C,weight%20change%20of%20%2D21.4%25.

[5] What to Expect when Starting Contrave, 2023. https://contrave.com/what-to-expect/#:~:text=*According%20to%203%20multicenter%2C%20double,and%20increased%20physical%20activity%2C%20the

[6] Pi-Sunyer, X., Astrup, A., Fujioka, K., Greenway, F., Halpern, A., Krempf, M., Lau, D.C., Le Roux, C.W., Violante Ortiz, R., Jensen, C.B. and Wilding, J.P., 2015. A randomized, controlled trial of 3.0 mg of liraglutide in weight management. *New England Journal of Medicine*, *373*(1), pp.11-22. https://www.nejm.org/doi/full/10.1056/nejmoa1411892

Active Ingredient (Brand Name)	Drug Class	Approval Date (dd/mm/yyyy) & Status /Review	Approval Indication(s)	Placebo-adjusted weight loss
Phentermine-topiramate (Qsymia)	Anorexiant	FDA 07/17/2012	Indicated as an adjunct to reduced-calorie diet and increased physical activity for chronic weight management in adults	3.5 - 9.3%[7]
Orlistat (Xenical)	Peripherally acting antiobesity agents	FDA 04/23/1999 Priority Review	Indicated for obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet	Approx 3%[8]

Off-label use of anti-obesity drugs

The intersection between diabetes and weight loss therapies became prominent as research recognized the interplay between obesity and insulin resistance.[9] Through a greater understanding of the mechanisms behind both obesity and diabetes, researchers found that medications initially designed for diabetes, such as semaglutide (a GLP-1 receptor agonist), had a notable effect on weight loss. Semaglutide, originally developed for the management of diabetes, epitomizes this shift from targeted diabetes management towards a focus on weight loss. Recognizing the greater market potential for this class of drugs, pharmaceutical companies sought additional marketing authorization for the drugs used in weight management.

Several medicines, originally approved for indications other than obesity, have shown to have been used off-label for weight loss. In short, the original studies of medication's effects extend beyond their original purpose. The off-label use of medications for weight management is exemplified in the cases of semaglutide (Ozempic), semaglutide tablets (Rybelsus), and tirzepatide (Mounjaro) (see Table 2).

---

[7] Qsymia, Study: EQUIP clinical trial, 2023. https://hcp.qsymia.com/efficacy-and-safety/study-equip/

[8] Finer, N., James, W.P.T., Kopelman, P.G., Lean, M.E.J. and Williams, G., 2000. One-year treatment of obesity: a randomized, double-blind, placebo-controlled, multicentre study of orlistat, a gastrointestinal lipase inhibitor. *International journal of obesity*, *24*(3), pp.306-313. https://pubmed.ncbi.nlm.nih.gov/10757623/

[9] Kahn, B.B. and Flier, J.S., 2000. Obesity and insulin resistance. *The Journal of clinical investigation*, *106*(4), pp.473-481.

Table 2: Off-Label Anti-Obesity Medicines

Active Ingredient (Brand Name)	Medication Class	Approval Date (dd/mm/yyyy) & Status/Review	Approval Indication(s)
Semaglutide (Ozempic)	Incretin Mimetic	FDA 12/05/2017	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Off-label use for weight loss
Semaglutide tablets (Rybelsus)	Incretin Mimetic	FDA 09/20/2019 Priority Review Status	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Off-label use for weight loss
Tirzepatide (Mounjaro)	Incretin Mimetic	FDA 05/01/2022 Priority Review Status	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Off-label use for weight loss

Rare genetic conditions causing obesity

Obesity also can have roots in rare genetic conditions, with nonalcoholic fatty liver disease (NAFLD), being one such condition. NAFLD manifests in two forms: either nonalcoholic fatty liver (NAFL) or nonalcoholic steatohepatitis (NASH).[10] Medication addressing the genetic roots of obesity requires a distinct therapeutic approach, such as underlying the genetic deficiencies responsible for excessive weight gain. While specific drugs for the treatment of NAFLD are currently unavailable on the market, there are promising developments in the pipeline.[11]

An example of a medication tailored for the generic origins of obesity is Setmelanotide (see Table 3). This drug is indicated for chronic weight management in those with Bardet-Biedl syndrome (BBS), pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency obesity in adult and pediatric patients 6 years of age and older. Setmelanotide targets a unique pathway in the brain that serves as the root cause of hunger and obesity in individuals with the aforementioned syndromes and deficiencies.

---

[10] NIH, Nonalcoholic Fatty Liver Disease (NAFLD) & NASH, April 2021. https://www.niddk.nih.gov/health-information/liver-disease/nafld-nash

[11] Akosua Mireku, NASH drugs race to cross the finish line, June 16 2023. https://www.pharmaceutical-technology.com/features/nash-drugs-race-to-cross-the-finish-line/ and Chew, N.W., Ng, C.H., Truong, E., Noureddin, M. and Kowdley, K.V., 2022, August. Nonalcoholic steatohepatitis drug development pipeline: an update. In *Seminars in Liver Disease* (Vol. 42, No. 03, pp. 379-400). Thieme Medical Publishers, Inc.. https://pubmed.ncbi.nlm.nih.gov/35709720/

Table 3: Orphan Drug Anti-Obesity

Active Ingredient (Brand Name)	Medication Class	Approval Date (dd/mm/yyyy) & Status/Review	Approval Indication(s)
Setmelanotide (Imcivree)	melanocortin 4 (MC4) receptor agonists	11/25/2020 Priority Review Orphan Status	Indicated for chronic weight management in adult and pediatric patients 6 years of age and older with obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency.

Cardiovascular Outcomes

Obesity is often associated with a number of complications, such as cardiovascular disease. As there is a growth in anti-obesity medicines and a shifting perspective of obesity as a disease warranting medicinal treatment,[12] there is a growing interest in assessing cardiovascular outcomes of obesity treatments.[13] A systematic review conducted by Wahab & le Roux (2022) revealed that the randomized controlled trials they examined demonstrated an improvement in cardiovascular outcomes when on obesity treatments. Furthermore, the review also highlighted the positive renal outcomes associated with GLP-1 drugs.

Researchers have acknowledged the 'protection' that anti-obesity drugs may offer, in terms of cardiovascular outcomes. This recognition could reshape how anti-obesity medication is used and to whom it is offered, for example through preventive cardiology.[14] More concretely, the recently announced Wegovy trial results indicate that the anti-obesity drug offers a reduction of major adverse cardiovascular events by 20%.[15] This bolsters Wegovy's image as not only a drug targeting individuals seeking weight reduction for reasons of aesthetics but also underscores measurable positive health outcomes. Eli Lilly is also assessing the

---

[12] FDA, One Health: It's for All of Us, 2023. https://www.fda.gov/animal-veterinary/animal-health-literacy/one-health-its-all-us#:~:text=In%202013%2C%20the%20American%20Medical,people%20that%20requires%20medical%20attention.

[13] Wahab, R.A. and le Roux, C.W., 2023. A review of the evidence on cardiovascular outcomes from obesity treatment. *Obesity Pillars*, p.100071. https://www.sciencedirect.com/science/article/pii/S2667368123000177

[14] Mariana Lenharp, "Anti-obesity drug also protects against heart disease — what happens next?", 10 August 2023, https://www.nature.com/articles/d41586-023-02528-2

[15] Novo Nordisk, "Novo Nordisk A/S: Semaglutide 2.4 mg reduces the risk of major adverse cardiovascular events by 20% in adults with overweight or obesity in the SELECT trial", 8 August 2023. https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-ir-materials/news-details.html?id=166301

efficacy and safety of tirzepatide and dulaglutide on cardiovascular risk, the study concludes in mid-2024.[16]

The implications of such findings extend beyond individual health, potentially influencing the landscape of public insurance coverage for Wegovy and future weight loss drugs that demonstrate similarly favorable cardiovascular outcomes. Overall, the evolving understanding of the benefits of anti-obesity drugs may reshape the consideration of subsidizing these medicines within public health systems.

Patent Landscape of Anti-Obesity GLP-1 Drugs

Method

The following section details the patent and exclusivity data for the three FDA-approved GLP-1 anti-obesity drugs. This methodology incorporates an analysis of the FDA-approved anti-obesity GLP-1 agonists using the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. To enhance the occurrence of analysis, a cross-referencing process was implemented with the use of Knowledge Ecology International's (KEI) database of the Orange Book List of Patents. This is a crucial step for identifying patents that have been deleted from the recent versions of the FDA Orange Book, where expired patents are removed due to expiration or other reasons. Since many of the patents are assigned to Novo Nordisk, the following data was also cross-referenced across the US product patents listed on Novo Nordisk's website.[17] The following section thus provides an overview of the patent landscape of semaglutide, liraglutide and tirzepatide.

Semaglutide Patent Landscape

Table 4. Semaglutide Patents

Assignee	Patent Number	Expiration Date	Title	Drugs Substance or Drug Product
Novo Nordisk	8,114,833	2025-08-13	Optimal For Production And For Use In Injection Devices	DP
Novo Nordisk	8,129,343	2031-12-05	Acylated GLP-1 compounds	DS

[16]NIH, A Study of Tirzepatide (LY3298176) Compared With Dulaglutide on Major Cardiovascular Events in Participants With Type 2 Diabetes (SURPASS-CVOT), 19 October 2023. https://www.clinicaltrials.gov/study/NCT04255433

[17] Novo Nordisk, Product Patents. https://www.novonordisk-us.com/products/product-patents.html

Assignee	Patent Number	Expiration Date	Title	Drugs Substance or Drug Product
Novo Nordisk	8,536,122	2026-03-20	Acylated GLP-1 compounds	DS
Novo Nordisk	8,579,869	2023-06-30 (expired)	Needle mounting system and a method for mounting a needle assembly	DP
Novo Nordisk	9,108,002	2026-01-20	Automatic injection device with a top release mechanism	DP
Novo Nordisk	8,684,969	2025-10-20	Injection device with torsion spring and rotatable display	DP
Novo Nordisk	8,920,383	2026-07-17	Dose mechanism for an injection device for limiting a dose setting corresponding to the amount of medication left	DP
Novo Nordisk	9,132,239	2032-02-01	Dial-down mechanism for wind up pen	DP
Novo Nordisk	9,457,154	2027-09-29	Injection device with an end of dose feedback mechanism	DP
Novo Nordisk	10,357,616	2024-01-20	Injection device with an end of dose feedback mechanism	DP
Novo Nordisk	9,687,611	2027-02-27	Injection device with torsion spring and rotatable display	DP
Novo Nordisk	9,775,953	2026-07-17	Dose mechanism for injection device for limiting a dose setting corresponding to the amount of medicament left	DP
Novo Nordisk	9,861,757	2026-01-20	Injection device with an end of dose feedback mechanism	DP
Novo Nordisk	10,220,155	2026-07-17	Syringe device with a	DP

Assignee	Patent Number	Expiration Date	Title	Drugs Substance or Drug Product
			dose limiting mechanism and an additional safety mechanism	
Novo Nordisk	10,335,462	2033-06-21	Use of long-acting GLP-1 peptides	DP
Novo Nordisk	10,376,652	2026-01-20	Automatic injection device with a top release mechanism	DP
Novo Nordisk	11,097,063	2026-07-17	Syringe device with a dose limiting mechanism and additional safety mechanism	DP
Novo Nordisk	11,311,679	2026-01-20	Automatic Injection Device With A Top Release Mechanism	DP
Novo Nordisk	11,446,443	2025-10-20	Injection device with torsion spring and rotatable display	DP
Novo Nordisk	RE46363	2026-08-30	Dial-down mechanism for wind-up pen	DP
Novo Nordisk	9,616,180	2026-01-20	Automatic injection device with a top release mechanism	DP
Novo Nordisk	7,762,994	2024-05-23	Needle mounting system and a method for mounting a needle assembly	DP
Novo Nordisk	9,687,611	2027-02-27	Injection device with torsion spring and rotatable display	DP
Novo Nordisk	9,764,003	2033-06-21	Use Of Long-acting GLP-1 Peptides	DP
Novo Nordisk	10,888,605	2038-08-24	GLP-1 Compositions And Uses Thereof	DP
Novo Nordisk	11,318,191	2041-02-17	GLP-1 Compositions And Uses Thereof	DP
Novo Nordisk	11,752,198	2038-08-24	GLP-1 Compositions	DP

Assignee	Patent Number	Expiration Date	Title	Drugs Substance or Drug Product
			And Uses Thereof	
Novo Nordisk	10,278,923	2034-05-02	Oral Dosing Of GLP-1 Compounds	DP
Novo Nordisk	10,933,120	2033-03-15	Compositions Of GLP-1 Peptides And Preparation Thereof	DP
Novo Nordisk	10,960,052	2031-12-16	Solid Compositions Comprising A GLP-1 Agonist And A Salt Of N-(8-(2-hydroxybenzoyl) Amino) Caprylic Acid	DP
Novo Nordisk	11,382,957	2031-12-16	Solid Compositions Comprising A GLP-1 Agonist And A Salt Of N-(8-(2-hydroxybenzoyl) amino)caprylic Acid	DP
Novo Nordisk	11,759,502	2033-03-15	Compositions Of GLP-1 Peptides And Preparation Thereof	DP
Novo Nordisk	11,759,501	2023-09-19 (expired)	Compositions Of GLP-1 Peptides And Preparation Thereof	DP
Novo Nordisk	11,759,503	2023-09-19 (expired)	Compositions Of GLP-1 Peptides And Preparation Thereof	DP
Novo Nordisk	9,278,123	2031-12-16	Solid Compositions Comprising A GLP-1 Agonist And A Salt Of N-(8-(2-hydroxybenzoyl) amino)caprylic Acid	DP
Novo Nordisk	10,086,047	2031-12-16	Solid Compositions Comprising A GLP-1 Agonist And A Salt Of N-(8-(2-hydroxybenzoyl) amino)caprylic Acid	DP
Novo Nordisk	6,899,699	2022-01-02 (expired)	Automatic Injection Device With Reset Feature	DP
Novo Nordisk	8,672,898	2025-10-03	Automatic Injection	DP

Assignee	Patent Number	Expiration Date	Title	Drugs Substance or Drug Product
			Device With Reset Feature	
Novo Nordisk	9,486,588	2022-02-01 (expired)	Automatic Injection Device With Reset Feature	DP
Novo Nordisk	D724,721	2029-03-17	Injection Device	DP
Novo Nordisk	D758,571	2031-06-07	Injection Device	DP
Novo Nordisk	D906,513	2035-12-29	Pill	DP
Novo Nordisk	D947,358	2037-03-29	Pill	DP

Patent Dispute

The U.S. Patent Office's Patent Trial and Appeal Board rejected challenges from Mylan Pharmaceuticals, owned by Viatris, against two key patents held by Novo Nordisk for the active ingredient in its drugs Wegovy and Ozempic. The Appeal Board has agreed to an *inter partes* review of the validity of a Novo Nordisk patent (US No. 10,335,462) related to dosage regimes for its diabetes and weight-loss drugs, Ozempic and Wegovy.[18]

Drug Shortage and Compounding

Semaglutide injection (Ozempic and Wegovy) is currently listed by the FDA as a drug shortage, the reason for the shortage is cited to be due to the "demand increase for the drug".[19] As a result of this shortage, compounding pharmacies are allowed to buy semaglutide from pharmaceutical ingredient manufacturers, compound the product, and market it lawfully, pursuant it meets certain conditions of the FD&C.[20] The prices of compounded semaglutide are drastically lower, ranging from $100 to $500 per month (versus $1,300 a month for the brand-name product).

Interestingly, at the same time, the frequency of prescriptions of older weight-loss drugs has increased (although on a more modest scale).

---

[18] Mylan Pharmaceuticals Inc v. Novo Nordisk A/S, Patent Trial and Appeal Board, No. IPR2023-00724.
[19] FDA Drug Shortages, 26 January 2024. https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Semaglutide%20Injection&st=c
[20] FDA, Semaglutide Letter, October 10 2023. https://www.fda.gov/media/173486/download?attachment

Generica Semaglutide

Semaglutide faces a patent expiration in 2032. Despite this, in January 2022, Rio Biopharmaceuticals, Aurobindo Pharma, Sun Pharmaceutical and Zydus Worldwide filed ANDAs for semaglutide. In December 2022, Mulan notified Novo Nordisk of their ANDA filing for semaglutide with the FDA.[21]

Liraglutide Patent Landscape

Table 5. Liraglutide patents

Assignee	Patent Number	Expiration Date	Title	Drugs Substance or Drug Product
Novo Nordisk	6,268,343	2022-08-22 (expired)	Derivatives Of GLP-1 Analogs	DS
Novo Nordisk	7,762,994	2024-05-23	Needle Mounting System And A Method For Mounting A Needle Assembly	DP
Novo Nordisk	8,114,833	2026-09-12	Propylene Glycol-containing Peptide Formulations Which Are Optimal For Production And For Use In Injection Devices	DP
Novo Nordisk	8,579,869	2023-06-30 (expired)	Needle mounting system and a method for mounting a needle assembly	DP
Novo Nordisk	8,684,969	2025-10-20	Injection Device With Torsion Spring And Rotatable Display	DP
Novo Nordisk	8,920,383	2026-07-17	Dose Mechanism For An Injection Device For Limiting A Dose Setting Corresponding To The Amount Of Medicament Left	DP
Novo Nordisk	9,108,002	2026-01-20	Automatic Injection Device With A Top Release Mechanism	DP

[21] Novo Nordisk, SEC Form 20-F, November 2022, https://www.sec.gov/ix?doc=/Archives/edgar/data/353278/000162828023001868/nvo-20221231.htm

Assignee	Patent Number	Expiration Date	Title	Drugs Substance or Drug Product
Novo Nordisk	9,132,239	2032-02-01	Dial-down Mechanism For Wind-up Pen	DP
Novo Nordisk	9,457,154	2027-09-27	Injection Device with an end of dose feedback mechanism	DP
Novo Nordisk	9,616,180	2026-01-20	Automatic Injection Device With A Top Rele	DP
Novo Nordisk	9,687,611	2027-08-21	Injection Device With T	DP
Novo Nordisk	9,775,953	2026-10-17	Dose Mechanism For An Injection Device For Limiting A Dose Setting Corresponding To The Amount Of Medicament Left	DP
Novo Nordisk	9,861,757	2026-01-20	Injection Device With An End Of Dose Feedback Mechanism	DP
Novo Nordisk	9,968,659	2037-01-09	Liraglutide In Cardiovascular Conditions	DP
Novo Nordisk	10,220,155	2026-07-17	Syringe Device With A Dose Limiting Mechanism And An Additional Safety Mechanism	DP
Novo Nordisk	10,357,616	2026-01-20	Injection device with an end of dose feedback mechanism	DP
Novo Nordisk	10,376,652	2026-01-20	Automatic injection device with a top release mechanism	DP
Novo Nordisk	11,097,063	2026-07-17	Syringe device with a dose limiting mechanism and additional safety mechanism	DP
Novo Nordisk	11,311,679	2026-02-02	Automatic Injection Device With A Top	DP

Assignee	Patent Number	Expiration Date	Title	Drugs Substance or Drug Product
			Release Mechanism	
Novo Nordisk	11,446,443	2025-10-20	Injection device with torsion spring and rotatable display	DP
Novo Nordisk	RE46363	2026-08-30	Dial-down mechanism for wind-up pen	DP
Novo Nordisk	9,265,893	2032-09-23	Injection Button	DP
Novo Nordisk	6,458,924	2017-08-22 (expired)	Derivatives Of GLP-1 Analogs	DS
Novo Nordisk	6,899,699	2037-05-12	Automatic Injection Device With Reset Feature	DP
Novo Nordisk	7,235,627	2019-03-04	Derivatives Of GLP-1 Analogs	DS
Novo Nordisk	8,672,898	2025-10-03	Automatic Injection Device With Reset Feature	DP
Novo Nordisk	8,846,618	2022-06-27 (expired)	Stable Formulation Of Modified GLP-1	DP
Novo Nordisk	9,486,588	2022-01-02 (expired)	Automatic Injection Device With Reset Feature	DP
Novo Nordisk	D724,721	2029-03-17	Injection Device	DP
Novo Nordisk	D758,571	2031-06-07	Injection Device	DP
Novo Nordisk	D734,450	2029-07-14	Injection Device	DP
Novo Nordisk	RE 41,956	2021-01-21 (expired)	Dose setting limiter	DP
Novo Nordisk	D952,835	2017-05-24	Injector pen	DP

Generic Liraglutide

In 2017, Teva filed an ANDA for liraglutide for the treatment of type 2 diabetes. However, following a settlement reached between Novo and Teva, the generic entrant is expected at the earliest in June 2024. In 2019, Mylan also filed an ANDA and thereafter a petition for Inter Partes Review against a formulation patent. Pfizer soon joined this Inter Partes Review. In 2021, Novo entered into a settlement with Mylan and Pfizer. Sandoz also filed an ANDA

for liraglutide.[22] As such, the liraglutide drug compound patents expired in 2023 in the US and Germany and were already expired in China and Japan.

Overlapping Patents for Liraglutide and Semaglutide

There are a couple of patents forming part of Novo Nordisk's GLP portfolio that overlap across their weight loss drugs. For semaglutide, there are 34 listed patents, and for liraglutide there are 37 listed patents. Of these, 24 of the patents overlap and belong both to liraglutide and semaglutide.

Tirzepatide Patent Landscape

Table 6. Tirzepatide patents

Assignee	Patent Number	Expiration Date	Title	Drugs Substance or Drug Product
Lilly	9,474,780	2036-01-05	GIP and GLP-1 co-agonist compounds	DS
Lilly	8,734,394	2031-02-24	Automatic injection device with delay mechanism including dual functioning biasing member	DP
Lilly	9,402,957	2031-06-29	Automatic injection device with delay mechanism including dual functioning biasing member	DP
Lilly	11,357,820	2039-06-14	GIP/GLP agonist compositions	DP
Lilly	11,084,861	2039-07-22	GIP/GLP1 co-agonist compounds	
Lilly	20230355719	Pending	Therapeutic uses of tirzepatide	

Drug Shortage

Similarly to semaglutide, tirzepatide is also listed by the FDA as currently in shortage. The FDA has cited that this shortage is due to the demand increase for the drug and that they expect limited availability through early 2024. As a result of this shortage, compounding pharmacies are allowed to buy semaglutide from pharmaceutical ingredient manufacturers, compound the product and market it lawfully, pursuant it meets certain conditions of the

[22] Novo Nordisk, SEC, Form 20-F, November 2022
https://www.sec.gov/ix?doc=/Archives/edgar/data/353278/000162828023001868/nvo-20221231.htm

FD&C. The compounded versions of tirzepatide have drastically lower prices, ranging from $130 - $350 per month, versus a list price of $1,060 for the branded version.[23]

Pipeline of Anti-Obesity Drugs

Anti-Obesity Drugs in the Pipeline

There is a robust pipeline of anti-obesity drugs in development. The information gathered in the table below focuses exclusively on pharmaceuticals developed as anti-obesity medications, excluding products whose primary endpoints or focuses are on Type 2 diabetes. Additionally, the scope of inclusion for the table below deliberately omitted products only being evaluated with regard to genetic causes of obesity, such as NASH (non-alcoholic steatohepatitis). There is an extensive pipeline of antiobesity drugs. While historically, there were Type 2 diabetes products that were thereafter indicated for anti-obesity, the following pipeline does not include products that are indicated for type 2 diabetes, but only those specifically being developed as an anti-obesity medication, excluding genetic causes of obesity such as NASH.

Table 7. Anti-Obesity Drug Pipeline

Therapy	Company	Mechanism of Action	Class	Expected Completion
Phase III				
Oral Semaglutide	Novo Nordisk	GLP-1R agonist	Incretin mimetic	Two Phase III studies completed, another Phase III study in progress
CagriSema	Novo Nordisk	Amylin analog and GLP-1R agonist	Amylin analog and Incretin mimetic	Phase II completed in 2022, Phase III ongoing (comparative trial)
Semaglutide 7.2mg (triple the current dose)	Novo Nordisk	GLP-1R agonist	Incretin mimetic	Phase III ongoing
mazdutide (IBI362)	Innovent Biologics	GLP-1R and GcgR dual agonist	Incretin mimetic	Phase II completed Phase III ongoing (GLORY-1) expected end date early 2024
Orforglipron (LY-3502970)	Eli Lilly	GLP-1R agonist	Incretin mimetic	Phase II completed Multiple Phase III trials ongoing,

[23] GoodRX Health, How Much Does Zepbound Cost Without Insurance, December 20, 2023. https://www.goodrx.com/zepbound/weight-loss-tirzepatide-cost

Therapy	Company	Mechanism of Action	Class	Expected Completion
				expected results in 2025
Retatrutide (LY-3437943)	Eli Lilly	GLP-1R/GIP/Glucagon triagonist	Incretin mimetic and glucose elevating agent	Phase II studies completed Phase III ongoing and expected completion in 2025-2026
Survodutide	Zealand Pharma and Boehringer Ingelheim	GLP-1R and GcgR dual agonist	Incretin mimetic	Phase III ongoing
efpeglenatide	Hanmi	GLP-1R agonist	Incretin mimetic	Phase III completed
Phase II				
Pemvidutide	Altimmune	GLP-1R/glucagon dual agonist	Incretin mimetic and glucose elevating agent	Phase II completed (obesity) Phase II ongoing (NASH)
danuglipron	Pfizer	GLP-1R agonist	Incretin mimetic	Phase II trials completed Pfizer looking into new release mechanism due to large amount of side effects
S-309309	Shionogi	MGAT2 inhibitor	Peripherally acting antiobesity agents	Phase II trial is ongoing and expected to be completed in early 2024.
AMG 133	Amgen	GLP-1R/GIPR dual agonist	Incretin mimetic	Phase I completed Phase II data expected in 2024
Bimagrumab	Eli Lilly	mAb	Activin receptor type-2B inhibitor	Phase II ongoing (obesity)
BI 456906	Boehringer Ingelheim	GLP-1R/glucagon dual agonist	Incretin mimetic and glucose elevating agent	One Phase II study completed and also currently being evaluated for other

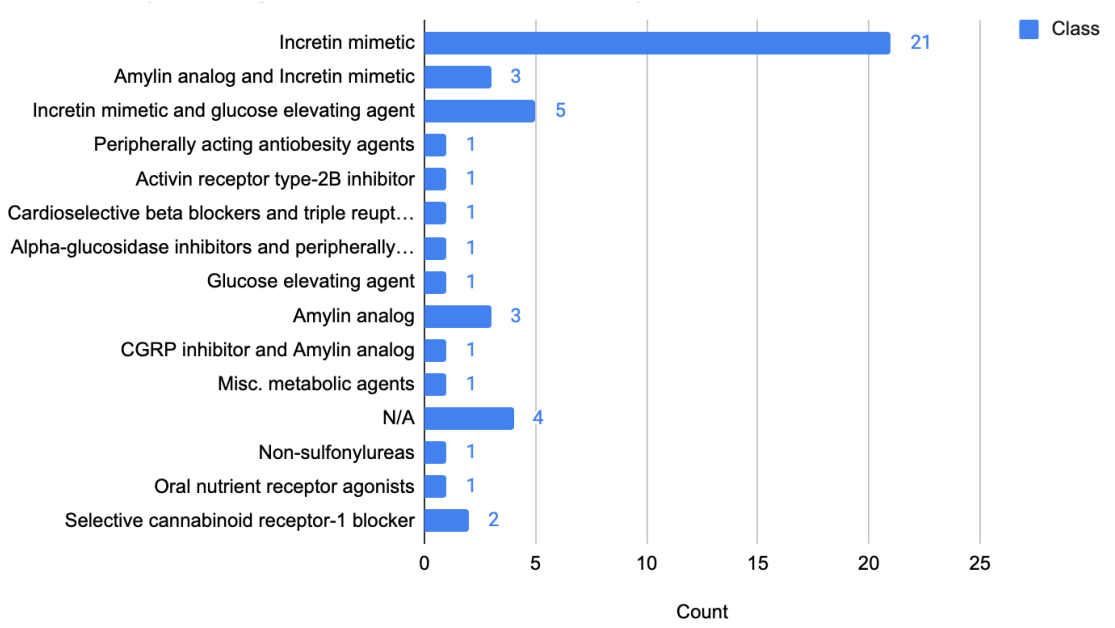
Therapy	Company	Mechanism of Action	Class	Expected Completion
				indications in phase II
Dapigultide	Zealand Pharma	GLP-1R/GLP-2R dual agonist	Incretin mimetic	Phase II ongoing
Tesomet	Saniona	fixed-dose combination of tesofensine and metoprolol	Cardioselective beta blockers and triple reuptake inhibitor of serotonin, norepinephrine, and dopamine	Phase IIb trials paused
EMP16	Empros Pharma	Fixed combination of orlistat and acarbose	Alpha-glucosidase inhibitors and peripherally acting antiobesity agents	Phase II completion in early 2024
ARD-101	Aardvark Therapeutics	TAS2R agonist	Incretin mimetic	Phase II completed
APH-012	Aphaia Pharma	oral glucose formulation	Glucose elevating agent	Phase II ongoing
CT-388	Carmot	GLP-1R/GIP dual agonist	Incretin mimetic	Phase II ongoing
GSBR-1290	Structure Therapeutics	GLP-1R agonist	Incretin mimetic	Phase II completed
Dapiglutide	Zealand Pharma	GLP-1/GLP-2 dual agonist	Incretin mimetic	Phase II
Phase I				
Amylin Agonist Long Acting	Eli Lilly	Amylin analog	Amylin analog	Phase I ongoing (indicated for obesity)
DACRA QWII	Eli Lilly	Dual amylin and calcitonin receptor agonists	CGRP inhibitor and Amylin analog	Phase I ongoing indicated for obesity
Petrelintide (amylin analog)	Zealand Pharma	Amylin analog	Amylin analog	Phase I ongoing for obesity

Therapy	Company	Mechanism of Action	Class	Expected Completion
Subcutaneous Amycretin	Novo Nordisk	Amylin analog and GLP-1R agonist	Amylin analog and Incretin mimetic	Phase I ongoing
Oral Amycretin	Novo Nordisk	Amylin analog and GLP-1R agonist	Amylin analog and Incretin mimetic	Phase I ongoing
DD01	D&D Pharmatech	GLP-1R and GcgR dual agonist	Incretin mimetic	Phase I
ERX-1000	ERX Pharmaceuticals	leptin sensitizer	Misc. metabolic agents	Phase I
GMA106	GMAXBIO	M-Body targeting both GIPR and GLP-1R	Incretin mimetic	Phase I
CB4211	CohBar Inc	MOTS-c analog	N/A	Phase I completed
CT-996	Carnot Therapeutics	GLP-1R agonist	Incretin mimetic	Phase I ongoing
CIN-109	CinRX	GDF-15 analog	Non-sulfonylureas	Phase I ongoing
NO-13065	Otsuka Pharmaceutical	Not stated	N/A	Phase I ongoing
SCO-267	SCOHIA	GPCR	Incretin mimetic	Phase I completed
K757	Kallyope	oral nutrient receptor agonists	Oral nutrient receptor agonists	Phase I ongoing
AMG-786	Amgen	Small molecule	N/A	Phase I
ECC5004	AstraZeneca & Eccogene	GLP-1R agonist	Incretin mimetic	Phase I ongoing
ZP8396	Zealand Pharma	Amylin analog	Amylin analog	Phase I

Therapy	Company	Mechanism of Action	Class	Expected Completion
INV-202	Inversage (bought by Novo)	CB1r agonist	Selective cannabinoid receptor-1 blocker	Phase Ib
Preclinical				
HM15136 + efpeglenatide	Hanmi Pharmaceuticals	glucagon analog/exendin-4 analog	Incretin mimetic and glucose elevating agent	Preclinical ongoing for obesity
HM15275	Hanmi Pharmaceuticals	GLP-1R/GIP/Glucagon triagonist	Incretin mimetic and glucose elevating agent	
ZP6590	Zealand Pharma	GLP-1R agonist	Incretin mimetic	GIP receptor agonist in preclinical development
LR19020	LG Chem	GPCR	Incretin mimetic	Preclinical
LR19156	LG Chem	Not stated	N/A	Preclinical
AGTX-2004	Agentix Corp	CB1R antagonist	Selective cannabinoid receptor-1 blocker	Preclinical completed
XW003 and XW017	Sciwind	GLP-1R/GIP dual agonist	Incretin mimetic	Preclinical

Upon analysis of the above preclinical outlook (Table 7) on anti-obesity medication, it was further categorized across the medication class. This distribution provides insight into the prevalence of different medication classes in the anti-obesity pipeline. The figure below illustrates the frequency distribution of medication classes within the dataset (see Figure 1).

Figure 1: Frequency of drug classes in the anti-obesity pipeline



Based upon Figure 1, the most frequently encountered drug class in the anti-obesity pipeline are incretin mimetics, which is the class of medicines most famous for GLP-1 agonists, such as semaglutide. This class includes dual and triple agonists, similar to the recently approved Zepbound, which is considered the next phase of incretin mimetic development. Further developments for incretin mimetics are ones that come in pill form, rather than an injection.

Additionally, the combination class of ‘Incretin mimetic and glucose elevating agent” is one of the more prominent pipeline classes, suggesting the growth of a more nuanced approach to both incretin and glucose modulation.

There were also a number of unique classes identified in the pipeline, namely, ‘Cardioselective beta blockers and triple reuptake inhibitors’, ‘Alpha-glucosidase inhibitors and peripherally acting antiobesity agents’, as well as ‘Oral nutrient receptor agonists’. This diversity highlights the various pathways by which researchers are exploring anti-obesity medicines, considering the complex interplay of different pathways involved in obesity, while also considering cardiovascular modulation.

Overall, the predominance of incretin mimetics shows a strong pipeline preference for following the same approach as the recent blockbuster GLP-1, whereby the drugs leverage the body’s ability to regulate appetite and glucose homeostasis.