

The Evolution of Anti-Obesity Medication (AOM) Access

In the past, obesity was considered a lifestyle choice, and access to AOMs was limited¹⁻³



Even after the recognition of obesity as a chronic condition, **some AOMs were withdrawn or not approved for long-term use** because the associated risks outweighed the benefits of treatment.^{1,4}



Many AOM treatments of the past were **excluded from federal and commercial health plans**, including Medicare Part D; access was very limited.^{5,6}



Obesity was **first defined as a disease by the National Institutes of Health in 1998**, followed by the American Obesity Society in 2008, and the American Medical Association in 2013.⁷

FDA-approved AOMs are required to demonstrate both weight-loss efficacy and safety.⁸

Currently, AOMs are more accessible than in the past and are intended for use with lifestyle modification^{3,9}

National medical associations^a agree that obesity is not merely a lifestyle issue, but a serious chronic disease requiring comprehensive treatment^{4,10}



The current Endocrine Society Clinical Practice Guidelines from the Pharmacological Management of Obesity emphasize the need to⁹:

- Manage obesity as **a medical condition**
- **Recommend pharmacotherapy** in addition to behavioral modification
- Highlight how AOMs may **amplify adherence to behavior change**

There is significant variability in coverage and reimbursement for AOMs across payers and plans, but currently **49% of private health plans cover AOMs.¹¹**



As of 2018, certain US government payers, such as TRICARE, have **expanded coverage and reimbursement** for AOMs.^{12,13}



AOMs have been, and remain, **excluded from Medicare Part D coverage²**



In response, the **Treat and Reduce Obesity Act (TROA)** has gained sponsors and support since it was proposed and aims to overturn this decision^{14,15}



In January 2023, the Federal Employees Health Benefits Program (FEHBP) stated that all federal health benefit carriers must¹³:

- Cover a range of AOMs on formulary^b
- Follow process- and evidence-based utilization management criteria for coverage that are transparent, readily accessible, and follow timelines for standard and expedited reviews



The FEHBP states that the **timely management of obesity may be cost effective**, lower health risks, and help prevent disease progression¹³

^aAmerican Medical Association (AMA), American Association of Clinical Endocrinology/American College of Endocrinology Obesity Task Force.

^bAs new AOMs are approved by the FDA, carriers should evaluate and update their coverage of AOMs.

Payers and employers **now have a wider range of AOM options** when building holistic health and weight-management programs⁸



Commercial and certain government health plans **have promoted coverage for obesity treatment**, including increased access to AOMs.^{6,9,12,13}



A trend of expanded coverage in government healthcare plans and commercial formularies to cover AOMs is growing¹⁶:

- In Q3 2021, **20 million people** with obesity had coverage for AOMs
 - By Q1 2023, or 18 months later, the coverage of AOMs had **doubled to 40 million people** with obesity
- Commercial lives that have opted in to AOM coverage **increased by approximately 25%** from January 2021 to October 2022, based on the claims approval rate

The FEHBP's guidance has changed over time, including the **recent update regarding the coverage of AOMs**.¹³

Nutrition and exercise are primary options

2011

Propose specific services to reduce the incidence of obesity

2012

Offer programs to help members attain and maintain a healthy weight

2013

Provide guidance on bariatric surgery

2014

May not exclude weight-loss drugs from coverage on the basis of obesity being a "lifestyle condition" or obesity treatment being "cosmetic"

2019

Must cover screening and intensive behavioral interventions if referred

2022

May not exclude AOMs based on a benefit exclusion or a carve out

2023

Provide adequate coverage of FDA-approved AOMs to meet patient needs

Carriers should offer adequate coverage for AOMs



Controlling and reducing the prevalence of obesity **may decrease associated healthcare expenditures** through potential improvements in comorbid conditions.¹⁷

Take action and cover AOMs for your employees or covered lives with obesity

- Identify your number of members or employees with obesity
- Understand your plan's or business's current AOM coverage and its integrated approach (opt-in or opt-out)
- See if your weight-management program meets or exceeds current guideline standards or the new FEHBP standard
- Customize your plan's approved medication list to include medically managed weight-loss and FDA-approved AOMs
- Ensure your prior authorization criteria align with label indications for proper utilization management of AOMs
- Access available tools and resources to demonstrate the potential benefits of covering AOMs in a real-world setting

Please contact your Novo Nordisk Account Manager for further details.

1. Colman E. Food and Drug Administration's obesity drug guidance document: a short history. *Circulation*. 2012;125:2156-2164. 2. Part D Drugs/Part D Excluded Drugs. Centers for Medicare & Medicaid Services. Published April 19, 2006. Accessed April 4, 2023. <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/PartDExcludedDrugs.pdf> 3. Dieguez G, Pyeneson B, Tomicki S, et al. Obesity in a claims-based analysis of the commercially insured population: prevalence, cost, and the influence of obesity services and anti-obesity medication coverage on health expenditures. *Milliman Report*. March 2021. 4. Recognition of obesity as a disease H-440.842. American Medical Association website. Accessed January 17, 2023. <https://policysearch.ama-assn.org/policyfinder/detail/obesity?uri=%2FAMADoc%2FHOD.xml-0-3858.xml> 5. FEHB Program Carrier Letter No. 2014-04. U.S. Office of Personnel Management. March 20, 2014. 6. Part D Drugs and Formulary Requirements. Centers for Medicare & Medicaid Services. Published January 15, 2016. Accessed April 10, 2023. <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf> 7. Rosen H. Is obesity a disease or a behavior abnormality? Did the AMA get it right? *Missouri Medicine*. 2014;11(2):104-108. 8. Tak Y, Lee SY. Anti-obesity drugs: long-term efficacy and safety: an updated review. *World J Mens Health*. 2021;39(2):208-221. 9. Apovián CM, Aronne LJ, Besesen DH, et al. Pharmacological management of obesity: an Endocrine Society clinical practice guideline [published correction appears in *J Clin Endocrinol Metab*. 2015;100(5):2135-2136]. *J Clin Endocrinol Metab*. 2015;100(2):342-362. doi:10.1210/jc.2014-3415 10. Mechanick JI, Garber AJ, Handelsman Y, Garvey WT. American Association of Clinical Endocrinologists' position statement on obesity and obesity medicine. *Endocr Pract*. 2012;18(5):642-648. 11. Gallagher Employer Market Intelligence: Employer Market Trends. Summer 2022. St Louis, MO: Benfield Research. 12. MTF formulary management for weight loss agents. Health.mil website. Published February 2018. Accessed March 1, 2023. <https://health.mil/Reference-Center/Fact-Sheets/> 13. FEHB Program Carrier Letter No. 2023-01. U.S. Office of Personnel Management. January 18, 2023. 14. Bajaj SS, Jain B, Kyle TK, Gallagher C, Stanford FC, Srivastava G. Overcoming congressional inertia on obesity requires better literacy in obesity science. *Obesity (Silver Spring)*. 2022;30(4):799-801. doi:10.1002/oby.23405 15. Cosponsors: H.R.1577 — 117th Congress (2021-2022). Congress.gov website. March 3, 2021. Accessed June 2, 2023. <https://www.congress.gov/bills/117/1577/congress/house-bill/1577/cosponsors> 16. Data on file. Novo Nordisk Inc.; Plainsboro, NJ. 2023. 17. Padula WV, Allen RR, and Nair KV. Determining the cost of obesity and its common comorbidities from a commercial claims database. *Clin Obes*. 2014;4(1):53-58.

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