The Management of Obesity for Appropriate Individuals: Sample Questions and Answers

Recently, there has been significant interest in anti-obesity medications (AOMs) from the general public, employers, and access stakeholders. In an effort to provide decision-makers like you with information you may need when considering a weight-management approach for your employees or members, we have created these sample Q&As. The topics covered include:

- Part 1: Impact of Weight Loss
- Part 2: AOMs for the Treatment of Obesity or Overweight
  - Section 1: Your Population and AOMs
  - Section 2: The Evolution of AOM Coverage
  - Section 3: Integrating AOMs Into Your Organization's Weight-Management Approach

Part 1: Impact of Weight Loss

Q1. What are the potential cost implications of weight loss?

Data indicate that weight loss of 5% to 10% can help curb the economic impact of costly comorbidities.[1,2] According to a modeling analysis, over a 10-year period in the United States, BMI reduction of 5% for an average adult BMI could potentially be attributed to 3.3 million avoided cases of coronary heart disease and stroke, resulting in ~$2.97 per member per month (PMPM) associated savings for health plans, as well as 4.1 million avoided cases of type 2 diabetes, resulting in ~$2.08 PMPM associated savings.[2,3] However, the economic benefits of sustained weight loss are contingent upon the appropriate weight-management approach being available for all obesity classes.

Study Designs:

2. Levi J, et al. F as in fat: how obesity threatens America's future. 2012.

   A 2012 report on the growing obesity epidemic in the United States was conducted by the Robert Wood Johnson Foundation and Trust for America's Health to raise awareness of the health and economic consequences of obesity. The report predicted the potential outcomes in the US if the average BMI were to decrease by 5% between 2010 and 2020, including the potential number of cases avoided and potential cost savings.[2]

Part 1: Impact of Weight Loss

Q2. How have obesity-related comorbidities been shown to impact healthcare costs?

The fastest growing obesity classes between 1998-2018 were Class II and III obesity.[4,5] These patients are at an increased risk for developing comorbid conditions and requiring additional healthcare resource utilization.[6,7] According to the Obesity Medicine Association, more than 200 comorbidities are associated with obesity.[8]

Patients diagnosed with obesity and other chronic conditions, such as hypertension and diabetes mellitus, are more likely to incur lifelong costs for comorbidities.[9] Patients with 1 or more comorbidities can expect an increase in total net expenditures. A retrospective claims study between 2006-2007 reported that for a single comorbidity, patients with obesity and hypertension observed a $5059 increase in total net expenditures, and patients with obesity with 2 comorbidities, diabetes mellitus and hypertension, observed an increase of $13,059.[9,a]

Efforts to reduce obesity prevalence and other comorbidities may result in net savings with sustained weight loss.[9,10] Controlling and reducing the prevalence of obesity may decrease other associated indirect expenditures, such as healthcare treatments and the claims and replacement costs associated with disability and workers' compensation, while also improving the general population's physical function and health.[1,9] Please contact your Novo Nordisk Account Manager for further information about the impact of reducing obesity in a real-world setting.

[a]Reported expenditures were adjusted for inflation to represent buying power equivalent to 2023 dollars.

Study Designs:

6. Guh DP, et al. *BMC Public Health*. 2009;9:88.

   In a study of weight-related comorbidities, a systematic review of 89 scientific articles was conducted to determine whether there were statistically significant associations related to obesity and overweight and 18 comorbidities were identified using a meta-analysis.[6]

7. Waters H, Graf M. America's Obesity Crisis. March 2018.

   To model the prevalence and economic effects of diseases related to obesity in 2016, CDC data regarding the prevalence of chronic health conditions was used to calculate the population attributable risk, while data from the Medical Expenditure Panel Survey and other studies provided the direct and indirect costs of medical treatment for different chronic health conditions.[7]

9. Padula WV, et al. *Clin Obes*. 2014;4(1):53-58.

   A retrospective commercial claims analysis was conducted using the Medstat MarketScan Commercial Claims and Encounter Database®. The mean net expenditures of obesity and select chronic conditions were calculated through 50,717 claims from working-age adults with obesity.[9]

10. Chen F, et al. *J Med Econ*. 2019;22(10):1096-1104.

    A simulation model informed and supported by a comprehensive literature review used data from the 2008-2016 National Health and Nutrition Examination Surveys (NHANES) of 2375 adults (≥65 years) who were eligible for anti-obesity interventions and had at least one complication of hypertension, dyslipidemia, or type-2 diabetes to model change in Medicare spending on AOMs over a 10-year period under different coverage scenarios.[10]

Part 1: Impact of Weight Loss

Q3. What are potential long-term outcomes of weight loss?

Studies have analyzed the relationship between weight loss and impact on weight-related comorbidities. Results showed even modest weight loss of 2% to >15% can yield clinically meaningful improvements in a number of the comorbidities associated with obesity.[11] At 1 year, 5% to <10% weight loss was associated with an increase in high-density lipoprotein, also known as the 'good' cholesterol.[12] At 1.5 years, patients with osteoarthritis experienced improvements in symptoms at >5% to >10% weight loss, including improved knee pain, functioning, speed, and walking distance.[13,14] Further, over a period of 3.2 years, for every kilogram (~2.2 lbs) of weight lost, there was a 16% reduction in risk for diabetes progression with maximal benefit at 10 kg (~22 lbs) weight loss, adjusted for changes in diet and activity.[11,15]

Study Designs:

11. Ryan DH, Yockey SR. *Curr Obes Rep*. 2017;6:187-194.

In a literature review, the relationship between weight-related comorbidities and the differences in improvement at 5%, 10%, and ≥15% in weight loss with medical weight management were assessed.[11]

12. Wing RR, et al. *Diabetes Care*. 2011;34(7):1481-1486.

In a 12-month multicenter, randomized clinical trial of adult patients (45-76 years, later increased to 55-76 years) with type 2 diabetes with overweight or obesity (BMI ≥25 kg/m^2 or ≥27 kg/m^2 if treated with insulin) (N=5145), the association between the magnitude of weight loss, changes in cardiovascular disease risk factors at 1 year, and the odds of meeting predefined criteria for clinically significant improvements in risk factors associated with type 2 diabetes were examined.[12]

13. Messier SP, et al. *Arthritis Rheum*. 2004;50(5):1501-1510.

In an 18-month, single blind, randomized control trial of adult patients (≥60 years) with overweight or obesity (BMI ≥28 kg/m^2) and knee osteoarthritis (N=316), the objective was to determine if long-term exercise and dietary weight loss are more effective, either separately or in combination, than usual care in improving physical function, pain, and mobility.[13]

14. Messier SP, et al. *JAMA*. 2013;310(12):1263-1273.

In an 18-month, single blind, randomized clinical trial of adult patients (≥55 years) with overweight or obesity (BMI 27-41 kg/m^2) and osteoarthritis (N=454), the objective was to explore if a ≥10% reduction in body weight induced by diet, with or without exercise, would improve mechanistic and clinical outcomes more than exercise alone.[14]

15. Hamman RF, et al. *Diabetes Care*. 2006;29(9):2102-2107.

In a Cox proportional hazards regression analysis of 1 arm (N=1079) of the diabetes prevention program, a randomized control trial over a 3.2-year period, the contribution of changes in weight, diet, and physical activity on the risk of developing diabetes among intensive lifestyle intervention in adult participants (≥25 years) with a BMI ≥24 kg/m^2 (≥22 kg/m^2 in Asian Americans) and impaired glucose intolerance were explored.[15]

Part 2: AOMs for the Treatment of Obesity or Overweight

Section 1: Your Population and AOMs

Q4. What percentage of my employees/members should I expect to use AOMs?

It's difficult to model the projected total use of AOMs in an employee/member population because, at present, data indicate that they are prescribed to only a small proportion of the eligible population. For instance, one study showed that AOMs are prescribed to less than 3% of the eligible population.[16] Another retrospective claims study showed only 2.4% of members with obesity had evidence of AOM utilization.[17]

Common modeling for utilization should include the entire category of medications used to treat obesity, including generics. According to IMS Health's Longitudinal Access and Adjudication Data (LAAD), about 20% of AOMs prescribed in 2022 were branded.[3] Generic AOMs compose approximately 80% of all prescriptions to treat obesity.[3] Given 1.9% prevalence of use on average for individuals with obesity, only 0.4% of a population are expected to be using branded AOMs.[3]

Study Designs

3. Data on file. Wegovy Market Share.

   AOM prescription data in patients with overweight or obesity (BMI >27 kg/m^2) was estimated using IBM Truven MarketScan® data for 1,242,910 individuals in IMS Health's Longitudinal Access and Adjudication Data (LAAD) database to evaluate market share, stay time, and discontinuation rates of anti-obesity medications.[3]

16. Saxon DR, et al. *Obesity (Silver Spring)*. 2019;27(12):1975-1981.

    To identify patterns of prescribing and usage rates of FDA-approved weight-loss medications between 2009 and 2015, data and prescribing patterns were evaluated for 2,248,407 patients from the Kaiser Permanente and Strategic Partners Patient Outcomes Research to Advance Learning (PORTAL) Obesity Cohort who were eligible to be prescribed weight-loss medications or who had received a weight-loss medication during the study period.[16]

17. Elangoven A, et al. *Obes Surg*. 2021;31:1105-1112.

    Trends in anti-obesity pharmacotherapy use, including following bariatric surgery, were assessed from 2010-2019, using data from Explorys®, a population-level commercial database. Trends in pharmacotherapy utilization were evaluated for patients with obesity as determined by a BMI ≥30 kg/m^2 (n=11,195,020) and were compared with adults with obesity who were prescribed anti-obesity drugs (n=274,160).[17]

Part 2: AOMs for the Treatment of Obesity or Overweight

Section 1: Your Population and AOMs

Q5. Are AOMs available through family coverage?

Family members who meet eligibility criteria receiving health insurance benefits under a family plan that covers AOMs would be eligible for this benefit.

Q6. How long is an employee/member expected to be on AOM therapy?

As with many types of treatments, the length of time an employee/member will require medication can depend on factors such as the type of medication and the physician-patient selected approach. Patients with clinically significant weight loss (considered as 5% or more of their starting weight) who do not experience side effects that prompt discontinuation may be advised by their healthcare provider to remain on the medication long-term for chronic weight management.[18] In a real-world analysis of more than 26,000 patients who were newly prescribed an AOM, less than 50% of patients remained adherent to their AOM treatment at 6 months.[19] Adherence rates for other chronic conditions, such as diabetes and hypertension, are similar, between 50% and 60%.[20]

Study Designs

19. Ganguly R, et al. *Diabetes Res Clin Pract*. 2018;(143):348-356.

    A retrospective analysis of 26,522 adult patients in the Truven Health MarketScan® claims databases evaluated prescription fill/refill data, days covered, and proportion of days covered during the first 6 months following the index claim (between January 2015 and March 2016) for an anti-obesity medication prescribed for long-term use.[19]

20. Kleinsinger F. *Perm J*. 2018;22:18-033.

    A healthcare communication provides a brief literature review and call to action regarding medication nonadherence for patients with chronic diseases.[20]

Part 2: AOMs for the Treatment of Obesity or Overweight

Section 2: The Evolution of AOM Coverage

Q7. How has formulary coverage for AOMs evolved over time?

While there is some variability in coverage and reimbursement for AOMs across payers and plans, coverage has increased over time. There have been substantial increases in coverage as clinical guidelines and certain government plans have recognized the impact of AOMs on chronic weight management and mandated coverage.[21,22]

Since AOMs are sometimes an excluded category of medications on many plans, the covered benefit for AOMs is extended through an addendum (for self-insured plans) or a rider (for fully insured plans).

Study Designs:

21. Dieguez G, et al. Milliman Report. March 2021.

    A summary of existing literature on the cost impacts of obesity, as well as an analysis of survey and claims data to quantify the prevalence of obesity among the commercially insured population and examine the influence of commercial insurance coverage of obesity services on health expenditures. The 2018 IBM® MarketScan® Commercial Claims Database and 2018 Milliman Consolidated Health Cost Guidelines™ Source Administrative Claims Database were used for an analysis of commercial plan engagement and obesity-related services, while data from NHANES were used to assess the prevalence of obesity in the commercially insured population.[21]

Part 2: AOMs for the Treatment of Obesity or Overweight

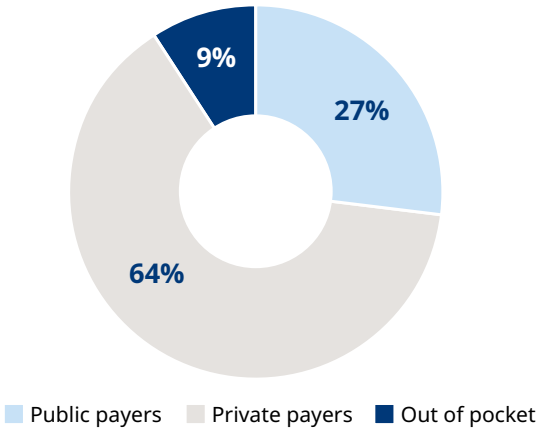
Section 2: The Evolution of AOM Coverage

Q8. What does formulary coverage for AOMs look like in government plans?

Since 2018, certain US government-sponsored healthcare plans, including TRICARE, have expanded coverage and reimbursement for AOMs.[23] As of [2023], AOMs are covered by Medicaid in [11] states, and additional states are expected to join in providing coverage in the future.[3]

With the gradual improvement in coverage for AOMs, government-sponsored healthcare have potential to see the benefits of decreased medical expenditures and increased economic efficiency as they address obesity. An analysis of data from the U.S. Medical Expenditure Panel Survey showed adult members with normal weight incurred half the amount of annual medical expenditures of adult members with obesity.[24] A simulation found that 100% uptake of AOMs could reduce Medicare and Medicaid spending and subsequently increase tax revenue over the study's evaluation period.[25]

Aggregate Medical Expenditures Due to Adult Obesity at National Level, by Payer[24]



Data are from the 2016 Medical Expenditure Panel Surveys (n=63,508) administered by the Agency for Healthcare Research and Quality, US Department of Health and Human Services.[24]

Study Designs:

24. Cawley J, et al. *J Manag Care Spec Pharm*. 2021;27(3):354-366.

    Estimates of the total amount and percentage of medical care expenditures directly attributable to obesity at a national level and in the 4 most populous states were modeled using a pooled cross-section of retrospective data from the Medical Expenditure Panel Survey from 2001 to 2016 that included 63,508 adults with at least 1 biological child in the household.[24]

25. Kabiri M, et al. *Inquiry*. 2021;58:46958021990516.

    The Health Economics Medical Innovation Simulation (THEMIS), an individual-level microsimulation model, estimated the impact of 100% uptake of AOMs on Medicare and Medicaid spending, disability payments, and taxes collected over a 75-year analytic period.[25]

Part 2: AOMs for the Treatment of Obesity or Overweight

Section 2: The Evolution of AOM Coverage

Q9. What does formulary coverage for AOMs look like in commercial plans?

Initial reactions in 2014 from the US Office of Personnel Management (OPM), on hearing Federal Employees Health Benefits (FEHB) carriers excluded coverage of weight-loss medications, said, "excluding weight-loss drugs from FEHB coverage on the basis that obesity is a 'lifestyle' condition and not a medical one or that obesity treatment is 'cosmetic,' is not permissible."[26]

In 2015, the Endocrine Society identified the pharmacological management of obesity as a "priority area in need of practice guidelines," and subsequently appointed a task force to develop their first Clinical Practice Guidelines for the Pharmacological Management of Obesity.[27] The guidelines emphasize the need for management of obesity as a medical condition; recommend pharmacotherapy in addition to diet, exercise, and behavioral modification; and highlight how AOMs may amplify adherence to behavior change.[27]

In early 2023, OPM released a new carrier letter updating the previous guidance.[22] The carrier letter states "FEHB Carriers must have adequate coverage of FDA approved anti-obesity medications on the formulary to meet patient needs and must make available their exception process to members….We recognize the progress made in covering anti-obesity medications; our goal is to have all Carriers offer adequate coverage."[22] Targeted policies promoting a broader range of obesity treatments, including AOMs, can equip the United States with the tools needed to combat the obesity crisis.[28]

Despite pressure for coverage, some insurance companies continue to push back against coverage for AOMs.[29] There is variability in coverage and reimbursement for AOMs across payers and plans; over [over 90%] of national pharmacy benefit managers now cover AOMs, while only [49%] of employers cover AOMs.[3,30]

Study Designs:

27. Apovian CM, et al. *J Clin Endocrinol Metab.* 2015;100(2):342-362.

    The Endocrine Society appointed a task force of experts to formulate evidence-based guidelines for the pharmacological management of obesity using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system to describe the strength of recommendations and the quality of evidence.[27]

28. National Association of Insurance Commissioners. 2022.

    The Toolkit for State Innovation was developed as a resource providing targeted options to address barriers to effective obesity treatment in a cost-effective and fiscally responsible manner through health policy for use by legislators, regulators, and other policymakers at the state level.[28]

29. Roser P, Bajaj SS, Stanford FC. *Int J Obes (Lond)*. 2022;46(9):1571-1572.

    The effects of coverage inequities for modern AOMs on patients with obesity was analyzed in a comment article, highlighting the need for international health policy changes to facilitate widespread coverage.[29]

30. Gallagher Research & Insights. Employer Market Intelligence. 2022.

    Results from an online survey of 97 jumbo employers (5000+ employees) and 30 employer health coalitions, as well as interviews with 8 employer benefit executives and 3 health coalition leaders provides an assessment of employer market trends and implications for manufacturers.[30]

Part 2: AOMs for the Treatment of Obesity or Overweight

Section 2: The Evolution of AOM Coverage

Q10. What criteria are typically included in prior authorizations (PAs) for AOMs?

PA criteria assure appropriate prescription refills and quantity limits are satisfied and provide a safeguard to align with label indications and to ensure that prescriptions are given to appropriate patients. PA criteria for AOMs typically follow the product's Prescribing Information and will include an individual's condition of obesity or overweight based on initial BMI and that the product should be used in conjunction with lifestyle therapy. PAs help to assure that the right patient can get a prescription at the right time. PAs also can be used to monitor continued efficacy over time.

Sample PA Criteria Based on BMI

	Obesity	Overweight
Adults (aged ≥18 years)	30 kg/m^2 or greater	27 kg/m^2 or greater In addition, 1 weight-related comorbidity (eg, hypertension, type 2 diabetes mellitus, or dyslipidemia) may also be considered as PA criteria
Adolescents (aged ≥12 to <18 years)	Initial BMI at the 95th percentile or greater for age and sex	

Q11. How will the market for AOMs evolve in the future?

AOM research is focused on the safety and efficacy of medications to promote weight loss and maintain weight over time.[18] Potential future medications are being investigated and may include different mechanisms of action.

Part 2: AOMs for the Treatment of Obesity or Overweight

Section 3: Integrating AOMs Into Your Organization's Weight-Management Approach

Q12. My organization offers behavioral-modification programs for people with obesity, but our employees are not using this benefit. What can we do?

Studies show that wellness programs alone are often insufficient in helping employees with obesity.[31,32] Although people with obesity may achieve weight loss through behavioral modification, metabolic and hormonal responses make weight loss difficult to maintain. Multiple factors affect weight loss and weight maintenance, including appetite signals, genetics, behavior, and environment.[33-37] However, existing behavioral-modification programs for obesity can become an important support offering to AOMs, since medical therapy like AOMs should be used in conjunction with a reduced-calorie diet and increased physical activity.[31,32] Providing coverage for AOMs, in addition to wellness programs, can give employees with obesity who require medical weight management the assistance they need.[31,32]

*Pharmacotherapy and lifestyle modifications combined **generally offer more weight loss and weight-loss maintenance** compared with lifestyle modifications alone.*[1]

Study Designs:

31. Jinnett K, et al. *Popul Health Manag*. 2019;22(4):308-314.

Data from online surveys using a cross-sectional, US-based stratified sample design were collected from October 29 to November 12, 2015, and used to describe the perspectives of adults (≥18 years) with obesity (n=3008) and employer representatives (n=153) on obesity, work impact, and corporate wellness offerings for obesity management.[31]

32. Wadden TA, et al. *N Engl J Med*. 2005;353(20):2111-2120.

In a 12-month randomized control trial to assess combined therapy for weight loss, adult patients (18-65 years) with obesity (BMI 30-45 kg/m^2) (N=224) were randomized into 1 of 4 treatment groups: sibutramine alone, lifestyle modification alone, combined therapy, or sibutramine plus brief therapy.[32]

Part 2: AOMs for the Treatment of Obesity or Overweight

Section 3: Integrating AOMs Into Your Organization's Weight-Management Approach

Q13. How do a weight-loss program and medical management program for obesity differ?

It's important to reverse the nationwide trend of increasing obesity prevalence and embrace what works. To reverse the trend, a comprehensive strategy and plan of action for weight management is required. By providing coverage of AOMs, wellness strategies, and medical treatments such as bariatric surgery, medical and prescription coverage policy criteria often combine typical weight loss approaches with more comprehensive medical solutions.

However, it is important to separate these 2 approaches from a policy and coverage perspective. While both are integral, an obesity medical management program includes a medical-strategy policy to provide treatment for a diagnosed medical condition and support those individuals for whom decreased calorie intake and increased physical activity have not been effective. Although people with obesity may achieve weight loss through behavioral modification, metabolic and hormonal responses make weight loss difficult to maintain. Multiple factors affect weight loss and weight maintenance, including appetite signals, genetics, behavior, and environment.[33-37]

Providing coverage of AOMs as part of an integrated platform of behavioral modification, nutrition counseling, and overall well-being can provide employees with obesity the support and assistance they need to help ensure success.

Q14. How do I check the Summary Plan or Certificate of Coverage (CoC) to determine if medically managed weight-loss services and FDA-approved prescription medications are excluded in my plan?

The CoC or Summary Plan document often commingles and/or excludes common preventative or medically managed weight-loss products and services with FDA-approved medications and proven medical interventions needed to support individuals who suffer from obesity and its comorbidities. Ask your carrier if you can customize your excluded list to include medically managed weight-loss and FDA-approved prescription medications.

Q15. Are there support programs that accompany AOM use?

Some branded products that treat chronic diseases, including obesity, provide patient support programs at no added cost to guide patients throughout their treatment journey.[38] Several weight-loss point solution vendors have now adopted a platform that includes AOMs as part of their engagement model. Check with your current or under-consideration vendors to see if they include AOMs as part of their overall comprehensive strategy.

Q16. If I have a High Deductible Health Plan (HDHP) with a Health Savings Account (HSA), are AOMs included on my primary Preventative Drug List?

A 2019 notice from the Internal Revenue Service (IRS) expanded the list of preventative care benefits permitted to be provided by a HDHP.[39] AOMs are not on this list; however, pharmacy benefit managers may choose to go beyond the IRS minimum requirements and customize their Preventative Drug Lists to offer AOMs.[39,40] Check your Preventative Drug List to determine if it can be customized to include AOMs.

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