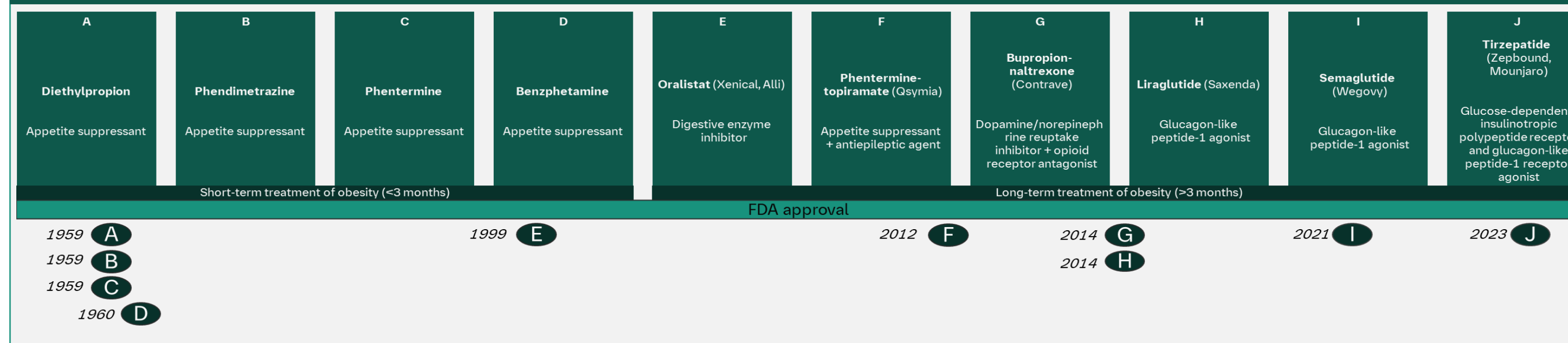


Introduction

- Currently, 42% of adults in the United States (US) are living with obesity.¹
- In 2016, nationwide medical spending for obesity and related comorbidities was \$261 billion.²
- Adults with a body mass index (BMI) of ≥ 27 kg/m² and \geq one obesity-related comorbidity (ORC) or BMI ≥ 30 kg/m² are eligible for anti-obesity medications (AOM) for short- or long-term weight management.³
- Novel and more effective AOMs showing larger weight loss over a longer duration are emerging that may lead to medical care cost savings (Figure 1).⁴⁻⁶
 - For example, a recent clinical trial showed that, relative to treatment with placebo, adults with obesity treated with semaglutide 2.4 mg can achieve on average a 12.4% (95% CI: -13.4 to -11.5; p=0.001) reduction in body weight over 64 weeks;⁷ findings which helped establish FDA approval of semaglutide as an AOM (Wegovy) in 2021.⁸
 - Weight loss can lead to medical care cost savings; both in the short term as a result of controlling HbA1C, blood pressure, and cholesterol, as well as over a person's lifetime through averting high-cost ORC (e.g., type 2 diabetes [T2DM], heart disease, and chronic kidney disease).⁹⁻¹¹
- A review of current AOM coverage policies and utilization rates, reflecting the current treatment landscape, in the US is needed.

Figure 1. Timeline of approved AOMs for short- and long-term weight management



Objectives

- To summarize AOM coverage policies and utilization rates in the US as of June 2023.

Methods

Coverage policies

- State Medicaid and commercial plan formularies were reviewed in May 2023 to identify coverage of AOM. Similarly to a review by Hughes et al (2022),¹² available state plans and formularies were identified through a search of health plan and government websites. The PICOS criteria guiding the review is presented in Figure 2a.
- For commercial insurance providers offering multiple plans with multiple formularies (i.e., individual/family, small group, large group, bronze, silver, platinum, etc.), the plan with the most comprehensive coverage was reviewed.
- Formularies were reviewed for listing of AOM (figure 1), restrictive criteria imposed (e.g. quantity limits [restricted amount of AOM covered], prior physician/specialist authorization, and step therapy [failure of other interventions before AOM coverage]),¹³ and drug tier (system indicative of level of co-payments).¹⁴
- Data were extracted and synthesized across all US states, stratified by AOM.

Utilization rates

- AOM utilization rates were identified by a targeted review of grey and published literature published before June 2023; see Figure 2b for PICOS.
- Utilization rates were reported using percentages overall and by payer. Other drivers of utilization rates were described as reported in the identified studies. Where rates were only reported over time, the most recent timepoint was extracted.

Figure 2: PICOS for (a) AOM coverage policies and (b) utilization rates

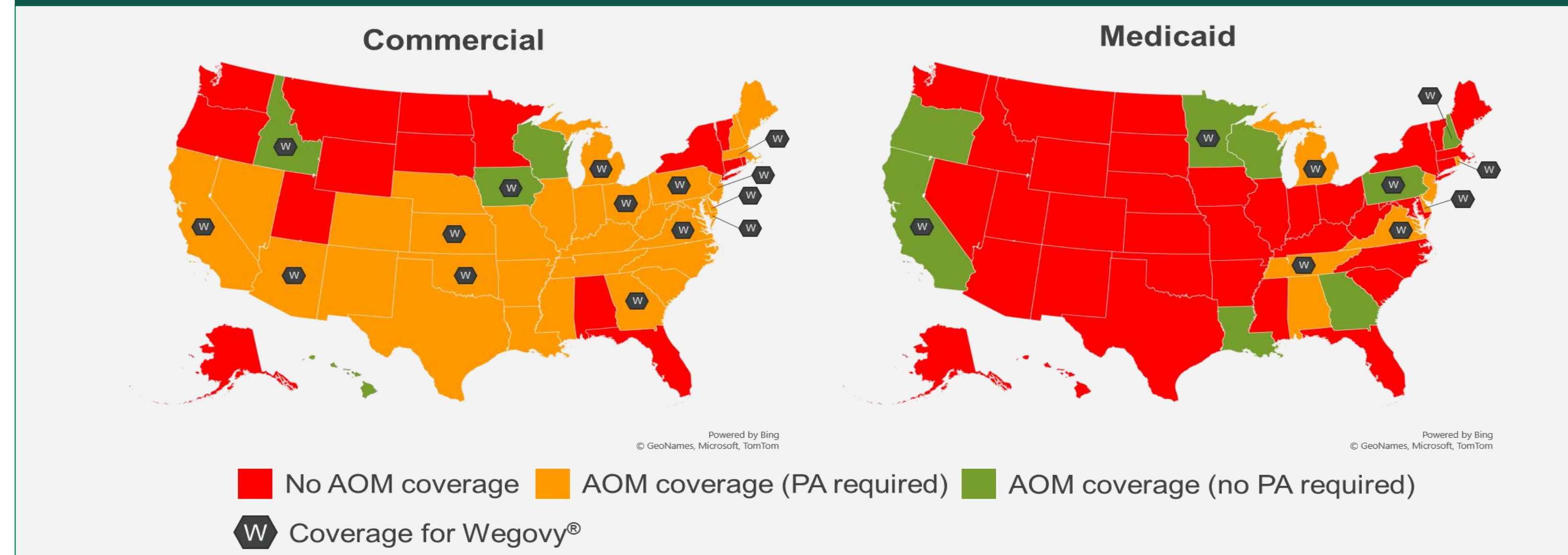
Category	Population	Intervention	Comparator	Outcome	Study design
a	Population: US Commercial and Medicaid plans	Intervention: AOM	Comparator: Not applicable	Outcome: Listing on formulary, restrictive criteria, drug tier	Study design: Grey literature (i.e., drug formularies)
b	Population: US adults eligible for AOM	Intervention: AOM	Comparator: Not applicable	Outcome: Utilization rate	Study design: Observational studies, grey literature

Results

Coverage policies

- Fifteen states had AOM listed on Medicaid formularies, and 35 states had AOM listed on commercial formularies.
- There was substantial variability in state level coverage, especially across commercial plans.
- Most AOM were listed as tier 3 or 4 (i.e., requiring higher co-payments) with multiple restrictive criteria applied:
 - Prior authorization and quantity limits were the most commonly applied restriction.
 - For example, seven commercial formularies were identified in Arizona. Of those seven, Wegovy was listed on three formularies. Wegovy was listed as tier 2 to 3 (medium to high co-payments), an approval process was required before Wegovy prescriptions could be filled (prior authorization), and only four prefilled subcutaneous pen injectors at a fixed dosage of Wegovy would be covered per year (quantity limits).
- In 22 states semaglutide and liraglutide were listed as an AOM (i.e., Wegovy, Saxenda) (Figure 3).

Figure 3: Commercial and Medicaid coverage of AOM in the US



Abbreviations: AOM, anti-obesity medication; PA, prior authorization; US, united states.

Table 1. Overview of study characteristics and utilization rates

Author, year	Study design	Sample population	Overall (Medicare, Medicaid, Commercial, and self-pay) or by payer	n	AOM utilization rate, %
Almazan, 2023 ¹⁷	All of Us research programme - EHR database analysis (2018-2022)	Adults with obesity	Overall	132,057	1.0
Dieguez, 2021 ¹⁵ *	NHANES retrospective survey analyses; IBM MarketScan + Milliman CHSD claims database analysis (1999-2018)	Commercially insured adults with obesity	Commercial	14.0 M	2.1
Lyu, 2022 ¹⁸	NHANES retrospective survey analysis (2009-2018)	Adults who are overweight or with obesity	Overall	12,133	0.5
Hughes, 2022 ¹²	Survey analysis using state entities and third-party plan carriers that held claims data for the employee health plans (2021)	Adults with obesity covered by employee health plan	Commercial + Medicaid	888,833	<1.0
Watkins, 2022 ¹⁹	MarketScan claims database analysis (2015-2019; 2 yrs follow-up)	Commercially insured adults eligible for AOM	Commercial	219,971	0.6
			Basic/major medical/ comprehensive	16,767	0.4
			Consumer-driven/ high-deductible	50,969	0.7
			Exclusive provider organization/ HMO	31,938	0.2
			Non-capitated point of service/ PPO	120,297	0.8
			Overall	6,331	1.3
			Medicare	1,653	0.1
MacEwan, 2021 ²⁰	NHANES retrospective survey analysis (2015-2018)	Adults eligible for AOM	Medicaid	978	0.9
			Commercial	3,051	1.2
			Self-pay	649	-
			Overall	11.2 M	2.4
			Medicare	2.1 M	1.3
Elangovan, 2021 ²¹	Explorys claims database analysis (2010-2019; 10 yrs follow-up)	Adults with obesity	Medicaid	1.2 M	2.1
			Commercial	5.9 M	3.1
			Self-pay	835,870	1.3
			Overall	-	2.6
			Commercial	-	2.6
Hampp, 2013 ²²	Health Vector One National (outpatient) claims database analysis (1991-2011; 20 yrs follow-up)	Commercially insured adults eligible for AOM	Commercial	-	2.6
US GAO, 2019 ¹⁸ *	MEPS retrospective survey analysis (2012-2016)	Adults with obesity	Overall	71.0 M	0.9

Notes: *Grey literature sources

Abbreviations: AOM, anti-obesity medication; BMI, body mass index; CHSD, Consolidated Health Cost Guidelines Databases; GAO, Government Accountability Office; HMO, health maintenance organization; IBM, international business machines; ICD, international classification of diseases; M, million; MEPS, medical expenditure panel survey; NHANES, national health and nutrition examination survey; ORC, obesity related comorbidity; PPO, preferred provider organization; US, united states; yrs, years.

Utilization rates

- Seven published studies and two grey literature sources characterizing utilization rates were identified (Table 1).^{12,15-22}
- In the US, utilization of AOM is generally considered to be low.
 - Six studies reported utilization rates overall among adults eligible for AOM;^{12,16-18,20,21} ranging from 0.5% among adults with a BMI of ≥ 25 kg/m² (2009-2018, NHANES)¹⁷ to 2.4% among adults with obesity (2010-2019, Explorys claims database).²¹
 - Five studies reported utilization rates by payer among adults eligible for AOM;^{15,19-22} ranging from 0.1% among adults eligible for AOMs (2015-2018; NHANES)²⁰ to 1.3% among adults with obesity (2010-2019, Explorys claims database)²¹ among those with Medicare coverage, 0.9%²⁰ to 2.1%²¹ among those with Medicaid coverage, and 0.6%¹⁹ to 3.1%²¹ among those with commercial coverage.
- While utilization rates specifically of Wegovy® were not identified, one study characterized utilization rates of semaglutide as an AOM among individuals with obesity but without T2DM by proxy.¹⁷
- Two studies reported on utilization rates over time (1991-2011).^{21,22} Both studies showed that phentermine was the most commonly dispensed AOM.
- Three studies explored AOM utilization rates by sociodemographic and economic characteristics.^{18,21,22} Across these three studies, AOM use was more common among women, individuals ≤ 50 years of age, individuals of Black or non-Hispanic race/ethnicity, those with insurance, with a higher self-reported education, with a higher household income.^{18,21,22}
- In a study from NHANES of adults eligible for AOM with commercial coverage, utilization rates were 0.6% overall.¹⁹ When stratified by plan type, utilization rates ranged from 0.2% (among those in an exclusive provider organization plan/health maintenance organization) to 0.8% (among those in a non-capitated point of service or preferred provider organization plan).¹⁹
- Authors suggested reasons for low utilization rates:

- High out of pocket costs and lack of coverage^{12,16,17,19}
- Limited experience with and knowledge of AOM from clinicians^{16,17,21}
- Stigmatization surrounding obesity^{12,20,21}
- User unawareness of, or vague language in plan documents that do not clearly indicate, coverage^{12,17}
- Safety and efficacy associated with AOM^{16,20}
- Prohibitive limitations^{12,15}

Conclusions

- Despite the availability of effective pharmacotherapy for weight loss, insurance coverage for AOM is sparse.
- An analysis of current utilization rates with the approval of Wegovy® is warranted, and strategies to increase equitable access to AOM are required to ensure patients in need can benefit from these effective weight loss therapies.

Limitations

- There was substantial variability in reporting methods and heterogeneity across commercial and Medicaid plan formularies.
- Some commercial formularies had restricted access and were not publicly available.
- Comparisons across studies was limited due to the variability of included AOMs (see Table S1 in supplemental material), sample population, study periods, and data sources.
- Only one study identified here included characterized utilization rates of semaglutide.¹⁷ In this study, the authors were not able to fully disentangle whether semaglutide was used as AOM or for T2DM/prediabetes, and therefore utilization rates in that study are likely underestimated.

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