Washington State Health Care Authority

Report to the Legislature

Anti-Obesity Medications in UMP

An analysis of possible coverage for drugs used to treat obesity on PEBB and SEBB's Uniform Medical Plans

Engrossed Substitute Senate Bill 5950; Sections 212(9), 213(2); Chapter 376; Laws of 2024

December 1, 2024

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Executive summary

Background

Engrossed Substitute Senate Bill 5950 (2024), Section 212(9) directs the Health Care Authority (HCA) to study and report options, and provide a recommendation, for covering glucagon-like peptide-1 agonists (GLP-1s) for the treatment of obesity for members of the Uniform Medical Plan (UMP).

> "[HCA] shall submit a report to the legislature describing options, and a recommendation, for possible future coverage in the uniform medical plan for food and drug administration approved glucagon-like peptide 1 agonists for the treatment of obesity and weight loss."

This report considers coverage options for treating obesity with GLP-1s with a recommended strategy if the Legislature pursues funding coverage. The workgroup expanded the scope of this report to include other anti-obesity medications (AOMs) that are not GLP-1s as part of the strategy recommended if coverage is established, as including other AOMs would be both fiscally and clinically responsible.

If coverage is created, our recommendation is to implement a customized prior authorization (PA) strategy, and to consider a supplementary lifestyle management program for complex cases. PA is a process that helps make sure that prescription drug benefits are administered as designed. Plan members receive a drug therapy that is safe and effective for their conditions, and that the treatment provides the greatest value. Some prescription drugs require PA to determine whether they are medically necessary and meet all applicable coverage criteria, or the plan will not cover them.

One alternative option is to allow coverage of AOMs in the UMP without requiring a PA, but HCA assumes this approach could lead to increased utilization of these medications and result in significant cost implications as members would be able to access AOMs without a review to ensure medications are clinically appropriate. Therefore, this is not a recommended approach; however, estimated modeled fiscal implications of this option is included in the report for context: Impacts of coverage without Prior Authorization (PA).

This report is due to the Legislature by December 1, 2024.

Recommended strategy if AOM coverage is funded: customized PA strategy

If the Legislature authorizes coverage of AOMs, we recommend instituting a customized PA strategy for GLP-1s to provide appropriate access and mitigate overprescribing in UMP. PAs are a common utilization management strategy to ensure a drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based best practice. They also ensure that high cost and/or high-risk drugs are tried after lower cost or more clinically effective alternatives.

Primary factors to control costs for GLP-1s to treat obesity are:

1. Restricting access to the drugs only to those for whom it is medically necessary.
2. Only covering the drug for as long as it is effective and well-tolerated.

Using PAs for AOM prescribing addresses these factors by:

1. First treating members through less costly alternatives.
2. Ensuring members are responding to the drug and discontinuing use quickly if ineffective or not tolerated.
3. Managing side effects in a timely manner.
4. Providing access to members for whom it is medically necessary.

The recommended PA cadence to achieve these goals is:

> **Step 1:** An initial PA to determine medical necessity (for both non-GLP1 AOMs and GLP-1 AOMs).
>
> **Step 2:** A PA review after three months of utilization to ensure positive member outcomes and progress in weight loss.
>
> **Step 3:** Subsequent PAs at six-month intervals.

PA content would be finalized closer to the time coverage is implemented so the most current best practices for this evolving treatment can be leveraged for the best possible health outcomes and cost-effectiveness.

While PAs do have an additional cost for each review, they still mitigate overall costs by ensuring medical necessity, appropriate step therapies, and clinical monitoring of treatment. Not using a PA process is assumed to increase utilization by approximately forty percent and is assumed to more than double the overall projected cost of a PA process. The additional members receiving GLP-1s in a non-PA scenario could be those that do not meet the clinical best practice criteria for treating obesity with GLP-1s, making the coverage fiscally and clinically less advisable.

Using PAs for AOMs could be supplemented by additional resources designed to assist members who are unsuccessful mitigating their obesity on the drug therapy in the PA approach alone. A third-party vendor who provides virtual resources and support for weight management could be procured to provide access to obesity medicine experts, trained support staff, and customized programs that include health coaching, biometric monitoring, and other interventions to find and customize the best treatment path.

The Employer Medical Contribution (EMC), which is the state's collectively bargained contribution towards the monthly premium for medical plan coverage, is expected to increase if AOMs are covered due to projected increased claims liability in UMP. Any claims liability for the fully insured plan offerings that exceeds the amount absorbed by the EMC will result in increased member premiums for members in those plans. Based on assumptions detailed in the report, the following is the assumed possible range of impact to EMC projected expenditures for both the PEBB and SEBB programs.

Estimated increase in EMC expenditures (state costs) for AOMs

	PEBB non-Medicare	SEBB actives	Total (PEBB + SEBB) annual increase
Low utilization scenario	$55,192,000	$73,862,000	$129,054,000
High utilization scenario	$111,489,000	$149,097,000	$260,586,000

We did not include assumptions for reduced future expenses for treatment of comorbidities related to obesity. These therapies are too new and there is insufficient peer-reviewed data to inform such assumptions.

Expected outcomes of our recommendation

Key benefits of this recommendation are the potential for supporting clinical efficacy and cost-effectiveness of GLP-1s in UMP through elimination of waste and avoidance of over-prescribing, and the relative ease of implementation.

Key challenges are the administrative cost for UMP, the provider impacts of PAs, and the potential for an increase in UMP plan enrollments from members seeking this coverage, increasing UMP claims costs.

Report workgroup recommendation

The primary recommendation answers the legislative request to determine the best possible prescribing strategy for GLP-1s in UMP. We also offer a recommendation enhancement for more targeted treatment of obesity in UMP. This option has a longer implementation time, additional ongoing costs, and adds methods to address obesity in our population. It answers the broader question behind the request for this report: how can we wholistically address obesity in UMP.

Recommendation: customized prior authorization program administered by UMP

Description

As of August 2024, there were 376,804 (65 percent) non-Medicare PEBB and SEBB members enrolled in a UMP plan offering; 2022 Center for Disease Control (CDC)[1] estimates suggest approximately 120,000 of them have obesity. To best protect both member health outcomes and cost-effectiveness, our recommendation is to implement a customized PA program administered by UMP.

PEBB and SEBB do not currently cover medications[2] prescribed for the purpose of treating obesity/weight loss in any of the self-insured (UMP) or fully-insured (Kaiser and Premera) medical plans. This restriction from coverage is an industry standard that exists as a rider in two-thirds of commercial insurance plans.[3] There is movement in the marketplace to start reversing these restrictions, but these changes are happening slowly. This does not mean that medications with weight loss indications are not prescribed in PEBB and SEBB, only that treatment of obesity cannot be the primary reason for the medication. For example, all PEBB and SEBB plans cover the treatment of type 2 diabetes with GLP-1s. While the individual may lose weight on the prescription, the goal is to treat their diabetes. To cover AOMs as a treatment for obesity in a future period, HCA would need to develop a detailed implementation plan that ensures member health outcomes are prioritized and the costs, safety, and side effects of the medications are understood and managed.

If the Legislature decides to approve coverage for AOMs, coverage prohibitions/riders would need to be removed from our UMP health plan coverage requirements, and the recommended PA criteria would need to be in place. We assume UMP will be allowed to prefer AOMs with a lower net cost over medications with higher cost, as is standard for many medication classes on formularies. Final PA criteria should be developed by Moda (UMP's pharmacy benefit manager [PBM]) and HCA clinical staff to make sure it reflects the best practices at the time coverage is initiated. Projected medication costs, utilization mix, and other aspects of the assumptions used to inform this analysis could change resulting in deviations from the projected results. HCA has listed the criteria and cadence that is best evidenced for success below, but this information could change prior to launching a prescribing program.

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[1] Adult Obesity Prevalence Maps | Obesity Statistics were state by state and prevalence stats specific to the State of Washington were used here.

[2] UMP currently offers these treatment options for obesity: bariatric surgery; Omada for Prediabetes and Omada for Diabetes Management; nutritional counselling services; and SmartHealth activities.

[3] Employer coverage for weight-loss drugs rises sharply, survey finds | Reuters

This option would provide access to AOMs for members seeking treatment, while ensuring the medications are used in a cost-effective and clinically appropriate manner. This method, however, relies on provider attestation that a member is engaged in lifestyle interventions in lieu of adding a more formal process through a vendor.

Suggested PA Cadence

PA type	Cadence	Purpose
Step 1: Initial	Before treatment begins	To ensure all relevant criteria are met and all step therapies have been performed.
Step 2: First reauthorization	Three months after treatment begins	To ensure that patient remains compliant with all concurrent requirements; to review patient progress; to determine if side effects need mitigation or if the drug should be discontinued.
Steps 3+: subsequent reauthorizations	Every six months after the first reauthorization at three months	To verify that the member is compliant with all concurrent requirements and that the members is still achieving ongoing clinically appropriate weight loss or maintaining successful weight loss goals. If the member has not achieved weight loss or has regained weight, coverage should end.

Suggested PA content

HCA holds the following as efficacious PA criteria (as of August 2024):

Initial PA criteria:

1. The member does not have type 2 diabetes (because the member can already access certain GLP-1s to treat their diabetes that also assist with weight loss).
2. Medication is not being used in combination with other medications indicated for obesity.
3. Attestation that a lifestyle treatment program was engaged in for at least three months and has been ineffective in attainment of a healthy weight status or improvement of weight-related comorbidities.
4. Medication is used as an adjunct to a reduced calorie diet and increased physical activity.
5. Member BMI is ≥30 kg/m^2 OR ≥ 27 kg/m^2 in the presence of at least one weight-related comorbid condition (e.g. dyslipidemia, hypertension, cardiovascular disease, obstructive sleep apnea).

6. Pediatric members (ages 12–17) must have a BMI at the 95th percentile for age and sex (for coverage of medications approved for that age range).
7. At least two less-expensive, non-GLP-1 AOMs (phentermine, Osymia, Xenical, Contrave, etc.) are ineffective, contraindicated, or not tolerated prior to approval of a GLP-1.

First-check and subsequent PA criteria:

1. Member is adherent to the requested medication.
2. Member and provider have discussed any side effects and their impact on the member.
3. For the first reauthorization, the member experienced a five percent or greater reduction in weight compared to baseline. For subsequent reauthorizations, the member maintains at least a five percent reduction in weight compared to baseline.
4. Medication is not used in combination with other medications that are indicated for obesity.
5. Documentation that member participates in a medically supervised intensive health behavior and lifestyle treatment program.
6. Medication is being used as an adjunct to a reduced calorie diet and increased physical activity.

Clinical impacts

If widespread access leads to providers prescribing these medications, without the clinical expertise to manage proper dose increases and adverse side effect management, there is potential for increased adverse side effects and poorer management of those effects in our populations. There is also still potential risk for shortages of the GLP-1s for members with diabetes given the increased demand by members for chronic weight management. This could result in possible increased diabetic complications in this member population and would need to be mitigated.

Fiscal impacts

During the 2024 legislative session, HCA completed fiscal modeling for proposed legislation that would require PEBB and SEBB fully insured health plans and UMP to provide coverage for GLP-1 and non-GLP-1 AOMs for the treatment of obesity (SB 6182). This modeling has been updated to adjust assumptions around medication cost and mix of utilization between non-GLP-1 and GLP-1 medications given the recommended structure of PA criteria. Given this discrete set of assumptions, detailed below, HCA identified two main cost implications facing UMP.

Increased PA costs

HCA assumes this coverage option would include a provision allowing UMP to require PA of AOMs for the treatment of obesity to ensure medical necessity when a member requests a prescription for a GLP-1 or non-GLP-1 AOM. Moda charges $50 per PA review. This cost analysis assumes PA would be required for GLP-1 and non-GLP-1 coverage determination in UMP using the criteria listed earlier in the section Suggested PA content.

PA costs are paid out of fund 439 (Uniform Medical Plan Benefits Administration Account) and fund 494 (School Employees' Benefits Board Medical Benefits Administration Account). UMP has already observed increased PA volume for PEBB and SEBB members seeking coverage of these medications for obesity. Adding PA requirements would further result in increased UMP administrative expenditures. The PA costs included in this fiscal analysis are assumed to capture the multistep PA process outlined above; this results

in administrative costs over and above what would be assumed if HCA were to singularly approve coverage of these medications through a standard PA protocol.

Given the assumed benefits of a customized PA protocol, HCA is confident that these costs will contribute to improved member outcomes and ensure members are appropriately managing their dosage. This methodology could impact use of additional healthcare services (e.g. emergency department visits, urgent care visits, treatment for adverse side effects, etc.), resulting in shifts in UMP claims liability not captured in this analysis.

Increased claims liability

UMP claims liability is assumed to increase significantly as a result of both the projected increase in utilization of AOMs including GLP-1s, and the associated cost of these medications. Increases to UMP claims liability will impact fund 721 (Public Employees' and Retirees' Insurance Account) and fund 493 (School Employees' Insurance Account). Furthermore, the state's contribution toward employee premiums is benchmarked off the UMP Classic (PEBB) and UMP Achieve 2 (SEBB) medical plans, and then applied uniformly across all plan offerings in the portfolio, any increases to claims liability will impact the projected cost of the state's contribution toward all employee medical premiums.

There is also the potential for increased cost liability in UMP resulting from use of other healthcare services due to adverse reactions or side effects associated with AOMs. No assumptions were made for estimated decreases in costs for presumed impacts to health outcomes in future years, and we have not sized the potential impact of treating adverse side effects for members using these medications. There is currently not enough evidence to model cost savings related to coverage of AOMs. Should cost avoidance be observed in future experience, it will be captured in actual claims liability and future UMP trends.

For the purposes of this analysis, the assumed net-of-rebate unit cost for a GLP-1 to treat obesity is approximately $776 per utilizing member per month. Non GLP-1s authorized for use by the Food and Drug Administration (FDA) for obesity are generally much lower in cost and are not assumed eligible for rebate, with unit costs ranging from less than $50 per month to approximately $620 per month; for the purposes of this cost analysis, it is assumed the average unit cost of a non-GLP-1 AOM is $218 per utilizing member per month.

According to the CDC, approximately 33 percent of Washington adults in commercial medical insurance plans are considered obese (defined as having a BMI of ≥ 30 kg/m^2 for adults or a BMI ≥95^{th} percentile for children). Given this assumption for prevalence of obesity, the relative size of the UMP population at the time of this analysis, data obtained from a recent survey of adults who are currently trying to lose weight, and assumptions gleaned from other analysis related to utilization of AOMs, the estimated utilization of AOMs in UMP is assumed to range between 5 and 10 percent of the PEBB and SEBB populations.

HCA's assumed annual utilization patterns are applied to a hypothetical cohort of utilizers (members who use an AOM) based on two distinct scenarios, explained below. The summarized projection of claims and PA liability results in an estimated range of potential annual impacts. These estimates are based on current assumptions, should actual results deviate from these estimates the results of this analysis will change.

- **Low Utilization Scenario:** Assumes 5 percent of the total PEBB and SEBB population would utilize an AOM per year.
- **High Utilization Scenario:** Assumes 10 percent of the total PEBB and SEBB population would utilize an AOM per year.

This analysis and all underlying utilization assumptions were applied in three steps to align with the customized PA criteria detailed above. PA costs and assumed increases in UMP claims liability were modeled at each step to assume a discrete subset of the population is utilizing either a non-GLP-1 AOM, GLP-1 AOM, or is non-adherent to either medication type in a stepwise approach:

- **Step 1:** Captures assumptions of utilization mix for the discrete cohort of assumed utilizers in each scenario. HCA's fiscal model intends to capture the proportion of the total cohort of utilizers who begin and continue using a non-GLP1 medication, begin or transition to a GLP-1 medication (resulting in an approved initial PA), or become non-adherent to AOMs during an initial period of 3 months.
- **Step 2:** Captures assumption for utilizers who remain adherent to either a non-GLP-1 or GLP-1 AOM and are approved for continued use after the three-month re-authorization review protocol.
- **Step 3:** Captures assumption for utilizers through the remaining annual period. Based on industry wide data, HCA assumes that non-adherence to medications increases after six months of utilization with the percentage of the original cohort remaining adherent assumed to be only 40 percent at the end of a 12-month period.

Projected UMP utilizers

	Total UMP population (As of July 2024)	Total assumed eligible for an AOM	Low scenario estimated utilizers	High scenario estimated utilizers
PEBB non-Medicare	250,000 members	80,850 members	12,128 utilizers	24,255 utilizers
SEBB actives	132,000 members	43,560 members	6,544 utilizers	13,068 utilizers

Based on the above assumptions, and the wide range of possible outcomes, the fiscal impact of this coverage option is difficult to estimate. Should any aspect of this analysis deviate from actual results, the resulting fiscal impact will change. Given what we know today, and the provided assumptions, HCA assumes the following range of fiscal impact.

Increased PA costs

Under the previously described utilization scenarios, HCA assumes annual PA costs in UMP will increase by the following.

Estimated Prior Authorization Increase in Expenditures

	PEBB non-Medicare	SEBB Actives	Total (PEBB + SEBB)
Low utilization scenario	$939,800	$506,400	$1,446,200
High utilization scenario	$1,879,800	$1,012,700	$2,892,500

Increased claims liability

Given the possible range of utilization of AOMs in UMP, and the assumptions applied to mix of utilization for AOMs and growth in the non-adherent population over each annual period, HCA assumes the total annual claims liability in UMP could increase by the amounts detailed below. These assumptions apply to the initial coverage year and into future annual periods. Until actual experience and utilization trends can be observed through claims experience it is unknown how future pharmacy trends and plan costs will be impacted.

Estimated annual increase in UMP claims liability

	PEBB non-Medicare	SEBB actives	Total (PEBB + SEBB) Annual Increase
Low utilization scenario	$48,844,000	$26,315,000	$75,159,000
High utilization scenario	$97,683,000	$52,629,000	$150,312,000

As plan cost liability increases in each of these plans, the state's contribution toward all employee medical premiums is also expected to increase. While the EMC is benchmarked off the UMP projected costs, it is applied to PEBB and SEBB member plan premiums across the non-Medicare portfolio resulting in an expenditure that is calculated using total population membership. Based on the assumed range of possible non-Medicare plan liability increases in UMP, it is assumed the EMC could increase by approximately three percent to six percent in the PEBB program and between four percent to seven percent in the SEBB program.

This increase may also impact our fully insured plan premiums. PEBB and SEBB fully insured carriers have alerted HCA of the potential for increases to member premiums if they expand their coverage to include AOMs. Kaiser Foundation Health Plan of Washington, Kaiser Foundation Health Plan of the Northwest, and Premera plans currently do not cover AOMs. It is assumed that should coverage be provided in the PEBB and SEBB fully insured plans in the future, there would be an increase to any plan's projected cost liability resulting in an increase to PEBB and SEBB member premiums. Based on the same analysis performed in the fiscal note for SB 6182, both Kaiser and Premera estimate a potential premium increase

ranging from approximately three to five percent, representing approximate premium increases of $22 to $28 per member per month (PMPM).

As UMP bid rates and the resulting EMC are expected to increase in each program resulting from projected increased claims liability, any claims liability for the fully insured plan offerings that exceeds that which is absorbed by the EMC will result in increased member premiums for members in those plans. Based on these assumptions, the following is the assumed possible range of impact to EMC projected expenditures for both the PEBB and SEBB programs:

Estimated annual increase in EMC expenditures (state costs)

	PEBB non-Medicare	SEBB actives	Total (PEBB + SEBB) annual increase
Low utilization scenario	$55,192,000	$73,862,000	$129,054,000
High utilization scenario	$111,489,000	$149,097,000	$260,586,000

Retirees who are not yet eligible for Medicare and enrolled in the non-Medicare risk pool pay the full cost of the non-Medicare bid rate; they do not receive an employer contribution and would incur significant increases in out-of-pocket premium costs resulting from coverage of AOMs in UMP.

The projected impacts of this recommendation do not include any assumption for the PEBB Medicare populations. During the 2024 board season, the PEBB board authorized resolution PEBB 2024-17 to allow the UMP Classic Medicare pharmacy benefit to transition from a creditable drug coverage offering to a Medicare Part D Employer Group Waiver Plan (EGWP). State laws (except as it relates to initial licensing and solvency) are pre-empted by federal laws for Medicare Advantage (MA) and Part D offerings. Coverage-related state laws are preempted under federal statutes and CMS regulations and therefore do not apply to federally regulated plans (42 U.S.C. § 1395w-26(b)(3); 42 U.S.C. § 1395w-112(g); 42 CFR 422.402; 42 CFR 423.440). Under current Medicare coverage requirements, coverage may be provided for GLP-1s that are FDA approved to treat obesity and type 2 diabetes if the member has type 2 diabetes or certain cardiovascular indications for members with excess weight or obesity. Per section 1860D-2(e)(2)(A) of the Social Security Act, AOMs are excluded from coverage under Medicare Part D formularies. Therefore, there are no assumed impacts to underlying claims liability for UMP Classic Medicare with Part D plan (PDP). However, should coverage of these medications be approved for the Medicare population, HCA assumes there will be impacts to retiree premiums. Medicare retirees enrolled in UMP Classic are currently realizing the full value of the Medicare explicit subsidy ($183). Therefore, assuming the Medicare explicit subsidy remains at the current $183, any increases in claims liability for UMP Medicare is assumed to be borne by retirees in the form of plan premium increases and will not be offset by the explicit subsidy.

Key Assumptions

- Unit costs of GLP-1 AOMs, net of assumed rebates, are currently estimated to be $776 per utilizing member per month. Unit cost of non-GLP-1 AOMs vary and is assumed to be approximately $218 per

utilizing member per month. These costs were provided by Moda. Should costs for these medications change in future periods, the results of this analysis will also change.

- HCA does not include any assumptions for cost offsets resulting from members who may discontinue use of maintenance medications to treat weight-related medical condition(s). While some evidence suggests the potential for improved outcomes, and therefore cost avoidance resulting from utilization of AOMs, there is contradicting evidence regarding the potential for increases in alternative healthcare services in the short term due to adverse effects of these medications.
- HCA also does not include any assumptions for cost offsets resulting in lower incidence of cardiovascular conditions, diabetes, or other complicating diagnoses related to obesity resulting from member utilization of GLP-1s and similar AOMs, for the same reasons stated above.
- HCA has modeled two distinct scenarios: (1) costs modeled with an assumption that requires PAs, and (2) costs modeled assuming no PA is required. These are distinct cost scenarios and HCA assumes that there could be increased utilization and costs associated with any coverage scenario that does not include PAs.
- HCA assumes the preferred drug list (PDL) could include preferred AOMs in any future formulary. Should preferred AOMs be prohibited, HCA assumes higher average drug costs potentially leading to downstream claims cost implications.
- HCA assumes between five percent and ten percent of the PEBB and SEBB populations could utilize AOMs.
- Given known side effects and possible adverse reactions to the medications, HCA assumes approximately 25 percent of members utilizing AOMs will discontinue utilization of medications six months after beginning a treatment course.
- Given known side effects and possible adverse reactions to the medications, HCA assumes 60 percent of members utilizing AOMs will discontinue utilization of medications twelve months after beginning a treatment course.
- HCA does not assume any future changes in enrollment, plan bid rates, or plan mix that may impact the results of this analysis.
- HCA does not make any assumption for the proportion of assumed eligible population who may already be taking a AOM for a diabetes diagnosis.

Assumptions for unit cost and rebates are based on current information and could change in future periods. HCA makes no assumptions for changes to drug cost or rebates for future periods. Should any aspect of this analysis deviate from actual results, the resulting fiscal impact will change.

Implementation timeline

This change would be implementable in our standard 2-year benefit change timeline, if funded. Health plan carriers would execute the majority of the implementation work as they would need to update systems to allow for claims adjudication, procedure updates in PA criteria, and customer service training. For HCA, plan changes requiring document updates would follow the usual annual preparation schedule for open enrollment. HCA would monitor the progress of the health plans in meeting the implementation

date. If the 2025 operating budget included the coverage change described in this report, the earliest coverage for AOMs could begin is January 1, 2027.

Health equity impact

Obesity and its comorbid conditions disproportionately affect historically underrepresented racial groups and families with lower incomes. Black adults have the highest occurrence of obesity adjusted for age and sex and Hispanic, non-White adults have the second highest occurrence.[4] In population studies of obesity it has been determined that adults without college degrees and/or with lower incomes had a higher occurrence of obesity.[5] Payors restricting coverage of AOMs exacerbates[6] an income-based inequity of access to methods to control obesity. Covering AOMs under a pharmacy benefit would close this gap and give members with the most statistical likelihood of obesity better access to treatment.

Mitigating additional anticipated costs for UMP is another equity issue. Improperly managed, this coverage could increase premiums to a degree that would make them unsustainable for some members necessitating a plan switch they would not otherwise desire.[7]

When pharmaceutical companies launched GLP-1 formulations for obesity, the increase in demand on the existing supplies created a shortage in GLP-1s to treat type 2 diabetes. Type 2 diabetes disproportionately affects communities of color and those with lower family incomes, creating another inequity around GLP-1 AOMs. People with the ability to pay out-of-pocket for GLP-1s were receiving the drug at the higher, obesity treatment, price point, and individuals with diabetes were left without access to vital medication to control their disease. Strategies to increase access to GLP-1s for obesity treatment need to ensure that they work to mitigate this downstream effect until manufacturing can meet demand.

Recommendation enhancement option: Procuring a vendor for complex cases

The recommendation for a customized PA structure fulfills the mandate of the legislative request, but the workgroup would like to offer an enhanced recommendation. If the Legislature would like to take a proactive approach to tackling obesity in UMP, there is an enhancement option that would provide a more wholistic approach to obesity treatment in our populations. We recommend offering a weight management lifestyle intervention program in conjunction with PA for AOMs. In this approach, the above PA program is still in effect, and members who seek medical treatment of obesity through AOMs would need to meet the PA conditions. One requirement of the PA would be that the member is enrolled in the obesity lifestyle intervention program. During concurrent PAs, the member must be engaged to an acceptable amount, determined by HCA, with the lifestyle intervention program.[8]

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[4] Prevalence of Obesity Among Adults, by Household Income and Education — United States, 2011–2014 | MMWR
[5] Ibid.
[6] Access to other resources to treat obesity without coverage on a health benefit (gym memberships, lifestyle interventions, etc.) is an existing societal, income-based inequity around addressing obesity.
[7] For example, a member may decide to switch from UMP Classic to UMP CDHP because they cannot afford the new premiums. However, since premium price and not health history drove their plan decision, they may be ill-equipped to meet the higher deductible and defer necessary care.
[8] An example of engagement may include utilizing at least one resource per month or connecting with their coach at least monthly

If an individual found their intervention with the AOMs was not effective and their re-authorization was rejected, the lifestyle intervention program would serve as another avenue to treat their obesity without surgical intervention. To accomplish this, UMP would also procure a third-party vendor for weight management with or without GLP-1s to address obesity treatment goals. This option may be considered as an available service for members who wish to utilize the service for weight management without utilizing medical intervention.

In this recommendation, enrollment in the third-party vendor's solution could be a PA requirement, and the program would be made available to members who did not receive approval for their concurrent PA or who seek a non-medical route towards achieving a lower BMI. This would grant the member access to a behavioral-based program which may be connected to their pharmaceutical obesity treatment as another option to address their condition. This has the added benefit of including enhanced intervention available for members who may need it.

This recommendation would take at least three years to implement as it would require a full procurement. In addition to a request for proposals (RFPs) it would be advisable to issue a request for information (RFI) to gain better insight into the available options in the marketplace. However, the PA itself could be initially implemented and the additional vendor could be rolled out at such time as it is procured.

Additional recommendation context

Impacts of coverage without Prior Authorization (PA)

One alternative to HCA's recommendation is coverage of AOMs without PA review for clinical necessity. This option would essentially allow any member to access medications for treatment of obesity, including GLP-1s, with a written prescription for the medication. HCA assumes this option would increase access to medications resulting in significant uptake in utilization and downstream fiscal impacts.

Similar to the analysis completed above, HCA modeled the potential impact of this option using an assumption that annual utilization patterns are applied to a hypothetical cohort of utilizers (members who use an AOM) based on two distinct scenarios, explained below. The summarized projection of claims and PA liability results in an estimated range of potential annual impacts. These estimates are based on current assumptions, should actual results deviate from these estimates the results of this analysis will change.

- **Low Utilization Scenario:** Assumes 7 percent of the total PEBB and SEBB population would utilize an AOM per year.
- **High Utilization Scenario:** Assumes 14 percent of the total PEBB and SEBB population would utilize an AOM per year.

It is assumed that 40 percent of all PA requests for AOMs would be denied; Therefore, should UMP implement coverage of AOMs not subject to PA, HCA assumes a 40 percent increase to utilization assumptions as modeled in the analysis presented above.

Projected UMP utilizers under a non-PA coverage scenario

	Total UMP population (As of July 2024)	Total assumed eligible for an AOM	Low scenario estimated utilizers	High scenario estimated utilizers
PEBB non-Medicare	250,000 members	80,850 members	16,979 utilizers	33,957 utilizers
SEBB actives	132,000 members	43,560 members	9,148 utilizers	18,295 utilizers

Based on the above assumptions, and the wide range of possible outcomes, the fiscal impact of this coverage option not subject to PA is difficult to estimate. Should any aspect of this analysis deviate from actual results, the resulting fiscal impact will change. Given what we know today, and the provided assumptions, HCA assumes the following range of fiscal impact. However, given PA would not be required for this coverage option HCA does not include any assumption for increased PA costs in UMP.

Increased claims liability

Under a scenario where UMP provides coverage for AOMs not subject to PA, HCA assumes the overwhelming majority of utilization will be observed in GLP-1 medications, as opposed to a mixed utilization of non-GLP-1 products and GLP-1s as detailed in the recommended coverage option. PA processes offer structure for the health plan, members utilizing medications and prescribing providers. Under a scenario where PA is not in place for these medications, HCA assumes some portion of the underlying projected increase in claims liability could represent unnecessary utilization that could have been avoided had a PA process been in place.

Given the costs associated with these medications, HCA assumes the total annual claims liability in UMP could increase by the amounts detailed below. These assumptions apply to the initial coverage year and into future annual periods. Until actual experience and utilization trends can be observed through claims experience it is unknown how future pharmacy trends and plan costs will be impacted.

Estimated Annual Increase in UMP Claims Liability

	PEBB non-Medicare	SEBB actives	Total (PEBB + SEBB) Annual Increase
Low utilization scenario	$129,976,000	$70,029,000	$200,005,000
High utilization scenario	$259,936,000	$140,047,000	$399,983,000

As plan cost liability increases in each of these plans, the state's contribution toward all employee medical premiums is also expected to increase. While the EMC is benchmarked off the UMP projected costs, it is applied to PEBB and SEBB member plan premiums across the non-Medicare portfolio resulting in an expenditure that is calculated using total population membership. Based on the assumed range of possible non-Medicare plan liability increases in UMP, it is assumed the EMC could increase by approximately eight percent to sixteen percent in the PEBB program and between nine percent to nineteen percent in the SEBB program.

As detailed above, UMP bid rates and the resulting EMC are expected to increase in each program resulting from projected increased claims liability. Any claims liability for the fully insured plan offerings that exceeds that which is absorbed by the EMC will result in increased member premiums for members in those plans. Based on these assumptions, the following is the assumed possible range of impact to EMC projected expenditures for both the PEBB and SEBB programs resulting from this coverage option:

Estimated annual increase in EMC expenditures (state costs)

	PEBB non-Medicare	SEBB actives	Total (PEBB + SEBB) annual increase
Low utilization scenario	$145,884,000	$195,066,000	$340,910,000
High utilization scenario	$292,860,000	$391,477,000	$684,337,000

All relevant impacts related to retirees not yet eligible for Medicare, self-pay members and PEBB Medicare retirees apply under this coverage option, as detailed above. Additionally, all underlying assumptions detailed in the summary of fiscal analysis for the recommended option apply to this analysis as well.

Non-fiscal impacts of prescribing AOMs without PAs

While this section is primarily a fiscal analysis of prescribing AOMs without an existing PA structure, the workgroup wanted to list our most significant concerns about this approach from clinical and policy perspectives as well. PAs for AOM prescribing verify medical necessity and ensure appropriate lower cost alternatives have been tried. Additionally, PAs allow the plan to monitor the patient's experience, ensuring the medication is well-tolerated and produces positive clinical outcomes. This process reduces waste in prescription drug spend and protects clinical outcomes. In addition to the above fiscal impact, the following concerns are critical in prescribing AOMs without PAs.

Clinical impacts of omitting PAs from strategy

- Prescribing AOMs without ascertaining medical necessity of the patient could result in:
  - Inappropriate utilization by members who are not obese.
  - Potential overutilization by members who are obese.
  - Potential abuse of the drugs by members who suffer from disordered eating.
  - All of the other issues, as listed below.
- Prescribing AOMs without utilizing appropriate step therapies could result in:
  - Patients who may benefit from lower cost alternatives would automatically step into higher cost drugs, leading to higher assumed claims liability for UMP and higher out-of-pocket costs for members.
  - Lower cost drugs may also treat the member's obesity with fewer side effects than GLP-1s and we have more information about their long term effects.
- Prescribing AOMs without appropriate clinical monitoring could result in:
  - Members may not benefit from the drug if they do not meet medical necessity but continue to take it.
  - Members who experience adverse health outcomes may not receive appropriate dose adjustments.
  - Members may not achieve the full benefit from the drug if they are not adherent.
  - Members may experience dangerous side effects and not seek treatment.

- The PA strategy is intended to ensure that all clinical recommendations are exercised in any AOM prescribing done by UMP. This best ensures member safety and clinical efficacy.

Policy impacts of omitting PAs from strategy

- The expected impact on premiums would be higher than that of a PA program, making the expected premium increases higher as well, creating greater economic inequity around plan selection.
- Current media attention around GLP-1s as a solution for obesity and the large proportion of the adult population who has obesity greatly exacerbates the demand for them. This reality creates a likelihood for significantly larger increases in utilization without a PA strategy in place to ensure medical necessity.
- By applying criteria less stringent than clinical best practice when prescribing a medication as controversial as an AOM, there is concern that UMP could be perceived as reckless with the safety of its members who have obesity.
- Without verification of the patient's medical necessity and monitoring by a physician and the expected demand for GLP-1s for obesity in the marketplace, there is greater potential for fraud.

Request for information (RFI)

An RFI would provide the opportunity to ask questions of vendors to gain insight into the most accurate utilization estimates and risks for covering AOMs in our population. Even if UMP does not pursue a vendor-based solution, an RFI would give us the opportunity to gain further insight into creating our own PA program by learning what necessary step therapies and concurrent requirements the industry is finding most successful.

Milliman analysis of strategy options

Milliman, one of HCA's contracted actuaries, has been engaged in the past to work through modelling options of large benefit changes for PEBB and SEBB. Using their services to further refine any recommendations in this report would offer more insight into the expectations laid out. Their input would also be beneficial when evaluating of the validity and scope of possible downstream savings in obesity-based claims stated as returns on investment (ROIs) against incurred costs when evaluating the value of these drugs.

Milliman has done extensive consulting work on best practices for payors covering AOMs balancing both clinical and fiscal goals. Engaging these services as part of a wider implementation plan of covering AOMs or other obesity treatment options in UMP would help to ensure that both clinical and fiscal best practices are implemented and ensure that modelling for expected costs and outcomes could be as accurate as possible.

Consideration of fully insured plan partners and the risk of bringing UMP out of parity with fully insured PEBB/SEBB plans

There are potentially significant impacts if UMP begins covering GLP-1s for obesity management and the fully insured plans do not. It is reasonable to assume members seeking GLP-1 coverage would switch from fully insured plans to UMP. If this occurs, these new UMP members will bring unanticipated, additional costs of their GLP-1 coverage into UMP claims. Additionally, the costs of any co-morbid conditions would

impact the UMP risk pool, resulting in increased estimated claims liability and therefore increased costs to the state.

UMP Medicare Part D considerations

To help control premium increases in the UMP Medicare plan, in 2024 the PEB board voted to make the UMP Medicare Plan a Medicare plan with Part D prescription coverage. This change to the UMP Medicare plan means that the prescription drug coverage for UMP Medicare is determined by CMS rules, which do not allow for the coverage of AOMs as of August 2024. If the decision is made to cover AOMs in UMP, it would create a disparity between our active UMP members and those on Medicare unless CMS changes their coverage rules for AOMs or a waiver is secured.

Background on AOMs

Obesity and its impacts on our populations

According to CDC estimates,[9] more than 120,000 members of UMP plans are considered obese, and another 130,000 are classified as overweight.[10] These designations are medical definitions regarding the amount of abnormal or excessive fat accumulation in the body that has been found to correlate with certain health risks. A BMI over 25 kg/m^2 is considered overweight, and over 30 kg/m^2 is classified as obese.[11] The US obesity rate increases by +2.1 percent per year and it is expected by 2035 that the national adult obesity percentage will rise to 58 percent.[12] Obesity has surpassed smoking as the number one cause of preventable disease and disability in the United States.[13]

Medical impacts of obesity

Obesity increases the risk of high blood pressure, high cholesterol, heart disease, type 2 diabetes, asthma, sleep apnea, osteoarthritis, musculoskeletal discomfort, gallbladder disease, stroke, certain cancers, depression, and anxiety.[14] Each 5 kg/m^2 increase in BMI above a BMI of 24.9 kg/m^2 has been associated with a significant increase in risk of mortality from coronary heart disease (CHD), stroke, diabetes mellitus, chronic kidney disease, and cancer. For BMIs between 30 kg/m^2 and 35 kg/m^2 expected life expectancy is reduced by two to four years, and for BMIs between 40 kg/m^2 to 45 kg/m^2 it is reduced by eight to ten years.[15]

Fiscal impacts of obesity

Obesity has substantial fiscal impacts on our populations as well. The global economic impact of obesity in 2020 was $1.96 trillion, or three percent of the global gross domestic product[16] (GDP) for one year of economic growth.[17] This is the same impact on GDP that Covid-19 had in 2020. In the US, obesity costs in 2022 were 3.5 percent of national GDP.[18] Direct medical costs of obestiy include treatment of comorbid conditions, obesity-related preventative care, and diagnostic services. Lost annual productivity costs among employees connected to absenteeism from obesity-related helath conditions and decreased productivity are estimated at $97-$132 per employe with obesity.[19]

[9] Adult Obesity Prevalence Maps | Obesity | CDC
[10] DNPAO Data, Trends and Maps: Explore by Topic | CDC
[11] Obesity (who.int)
[12] The future cost of obesity, according to a new report (advisory.com)
[13] Perreault, Leigh & Blandine Laferrére, Overweight and obesity in adults: Health Consequences
[14] Consequences of Obesity | Overweight & Obesity | CDC
[15] Ibid.
[16] GDP - The measure of the value of the goods and services produced by a specific entity over a defined time period.
[17] The future cost of obesity, according to a new report (advisory.com)
[18] Consequences of Obesity | Overweight & Obesity | CDC
[19] Ibid.

Types of medical obesity treatments

Comparison of obesity treatment options

Method	Reported weight reduction from clinical studies	Estimated treatment cost range	Treatment time range	Most common possible side effects	Rare but serious possible side effects	Current UMP obesity coverage
GLP-1 Agonists FDA approved for the treatment of obesity	5 percent to 20 percent	$1,060-$1,430 / month	56 weeks – lifetime treatment	Loss of appetite, nausea, vomiting, diarrhea, dizziness, mild tachycardia, infections, headaches, indigestion, injection site pain	Pancreatitis, medullary thyroid cancer, acute kidney injury, and recent concerns about gastroparesis (stomach paralysis)	No
Bariatric surgery	20 percent after 10 years	$29,198 - $34,398 in Washington State	Usually 1 procedure, sometimes revision needed	Infection, blood clots, leaks in GI system, gallstones, hernias, vomiting, acid reflux, ulcers	Bowel obstruction, dumping syndrome, reaction to anesthesia, hypoglycemia, excessive bleeding, death	Yes
Other FDA-approved AOMs (excluding setmelanotide[20])	Up to 9 percent over 56 weeks	$12.36/month - $667.84/month	12 weeks – lifetime treatment	Blurred vision, dizziness, anxiety, depression, lack of appetite, trouble sleeping, diarrhea, nausea, vomiting, muscle pain, urinary urgency, vaginal infections, dry mouth, changes in libido, erectile disfunction, change in taste, constipation, memory problems	Paranoid delusions, suicidal ideation, bloody urine, anaphylaxis, seizures, hallucinations	No
Lifestyle modification programs (plan provided)	10 percent in first 16-26 weeks	Approximately $15 Per Participant per Month (PPPM)	6 Months – Lifetime treatment	None	None	Many members with obesity without type 2 diabetes qualify for Omada for Prediabetes.

[20] This drug treats obesity that occurs in a rare genetic condition and would not be used to treat members with obesity who do not have the genetic condition. It is not compared to GLP-1s, as it is not an appropriate substitute.

Drug therapies with GLP-1s

A full list of FDA-approved AOMs can be found in Table 2: FDA-approved AOMs in the Appendix of this document. Current FDA-approved GLP-1s are listed in the chart below.

GLP-1s and their uses (as of September 2024)

Active ingredient	Brand name	FDA-approved indication
Liraglutide	Victoza	Type 2 diabetes
	Saxenda	Obesity
Semaglutide	Ozempic	Type 2 diabetes
	Rybelsus	Type 2 diabetes
	Wegovy	Obesity; Reduction of the risk of major cardiovascular events in adults with established cardiovascular disease.
Tirzepatide	Mounjaro	Type 2 diabetes
	Zepbound	Obesity

GLP-1s have been used to treat type 2 diabetes for nearly twenty years. These medications signal GLP-1 receptors throughout the body and cause the body to produce more insulin; block secretion of glucagon (a hormone that raises blood sugar); slow stomach emptying; and make the patient feel fuller longer. These effects not only treat type 2 diabetes, but also result in weight loss in many patients with obesity (with or without a type 2 diabetes diagnosis). In clinical trials, certain GLP-1s resulted in 15 to 20 percent weight loss in adults with obesity.[21] Separately, the FDA has approved GLP-1s specifically for treatment of obesity under some formulations as an adjunct to a reduced-calorie diet and increased physical activity.[22] Current research is being done into the efficacy of GLP-1s in treating heart disease, non-alcoholic fatty liver disease (NAFLD),[23] obstructive sleep apnea, and other obesity-related comorbidities. In March 2024, semaglutide, under the brand-name Wegovy, was approved by the FDA to reduce the risk of major adverse cardiovascular events in obese or overweight patients with a history of cardiovascular disease. Semaglutide has been shown to reduce major adverse cardiovascular events in adults with established cardiovascular disease who do not have diabetes and to improve symptoms and exercise function in some individuals with heart failure.

GLP-1s have been successful in creating weight loss results in patients where other interventions have failed. In clinical trials, GLP-1s have been associated with greater weight loss when compared to a placebo. Patients with obesity who experience weight loss often observe a reduction in the incidence, effects, and/or risks of obesity-related comorbidities like high blood pressure, high cholesterol, NAFLD, heart

[21] Weight loss between glucagon-like peptide-1 receptor agonists and bariatric surgery in adults with obesity: A systematic review and meta-analysis - PubMed (nih.gov)
[22] GLP-1 Agonists: What They Are, How They Work & Side Effects (clevelandclinic.org)
[23] Note: Medical literature is moving toward Metabolic dysfunction-associated steatotic liver disease (MASLD) as the new term for NAFLD.

disease, prediabetes/diabetes risk, obstructive sleep apnea, and kidney disease. However, there are industry-wide concerns about patients regaining lost weight upon stopping obesity treatment with GLP-1s. One study indicated that two-thirds of the weight lost was regained within one year of stopping treatment.[24]

The most often cited concerns about treating obesity with GLP-1s are non-adherence to use of the drug regimen as prescribed, side effects, weight regain after discontinuation, and cost. The most common side effect is mild to moderate gastrointestinal (GI) complications (nausea, vomiting, constipation, and/or diarrhea). These symptoms are associated with increasing doses and were mitigated by changing eating patterns to small frequent meals and/or slowing the rate at which doses were increased. Additionally, GLP-1s have been linked to more serious side effects like gastroparesis,[25] serious GI complications (nausea, vomiting, constipation, and/or diarrhea), pancreatitis, bowel obstruction, and thyroid cancer. Because of the delayed gastric emptying that occurs with GLP-1 use, a risk of food regurgitation and aspiration during anesthesia exists and patients having an elective surgical procedure are recommended to stop taking GLP-1s a week prior to surgery. The long-term side effects of obesity formulations of GLP-1s are still under investigation with little information available due to the short amount of time they have been studied. Although one of the "oldest" type 2 diabetes GLP-1s has been on the market for nearly twenty years, long term effects in populations with diabetes, who typically take a lower dose, are not yet exhaustively studied.

The reported weight loss found in GLP-1s is the average experienced in clinical trials that combined GLP-1 use with strict medically supervised lifestyle intervention programs that included diet and exercise monitoring along with side effect mitigation. Expectations of weight reduction would need to be managed when GLP-1s are prescribed to a less heavily monitored population. It is also possible a patient will experience no weight loss on these drugs. Regular work with a patient's care team may be required to determine appropriate treatment. Patients also may believe they will have significant results requiring less lifestyle interventions, fueled by current media attention on GLP-1s, than the evidence shows. This can contribute to more failures on the drug and wasted drug spend.

As of September 10, 2024, GLP-1 list prices for the obesity formulation range from $1,060–$1,430 per utilizing member per month, and there is evidence that discontinuation and/or non-adherence to a drug regimen can result in patients regaining some or all weight lost during use. In a study on deprescribing tirzepatide for obesity, the average participant regained 14 percent of their lost body weight in the first year after stopping the drug.[26] Some or most patients may be on these drugs long term to treat chronic conditions, which carries both increased long-term costs and health risks for any downstream side effects.

Two-thirds of commercial health plans nationally restrict the prescribing of all AOMs and only 13 states currently allow coverage of them for Medicaid.[27] There is currently a substantial inequity of access to GLP-1s for obesity based on income. Individuals with the financial means to pay for their GLP-1s out-of-pocket

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[24] Weight regain and cardiometabolic effects after withdrawal of semaglutide: The STEP 1 trial extension - Wilding - 2022 - Diabetes, Obesity and Metabolism - Wiley Online Library

[25] Defined as paralysis of the stomach that interferes with normal absorption and movement of food in the stomach. This condition sometimes persists despite discontinuation of the GLP-1.

[26] How Much Weight Comes Back After You Stop Using a Weight-Loss Drug? - The New York Times (nytimes.com)

can currently access independent vendors that provide GLP-1 prescribing for obesity without waiting for their plan to cover them.[28] This creates a great income-based inequity access for the treatment of obesity, a disease that disproportionately affects individuals in poverty. [29, 30]

Other drug therapies

GLP-1s are the AOMs most discussed currently, but there are other classes of AOMs on the market. Estimated monthly costs range from $12 to $3,623 per utilizing member per month with expected reductions in weight ranging from 5 to 18 percent.[31]

Other FDA-approved AOMs, which are also currently restricted from access on UMP plans, have shown some success with weight loss in patients with obesity. Stimulant-based appetite suppressants (benzphetamine, diethylpropion, phendimetrazine, and phentermine) are schedule III and IV controlled substances recommended for limited use due to side effects and potential for dependence. These FDA-approved AOMs have similar prescribing timelines to GLP-1s. All drugs in this category tend to take longer to achieve results than GLP-1s or bariatric surgery and, on average, achieve lower overall reductions in body weight. Like GLP-1s and bariatric surgery, they have the added limitation of functioning better with lifestyle interventions like diet change and increased physical activity than when used alone.

Some medications are being used for off-label application (prescribed for a condition that the drug is not FDA approved to treat) to help with weight loss, but weight loss is a side effect of the medication. To minimize off-label prescribing of GLP-1s, UMP requires that members have a diagnosis of type 2 diabetes before approving payment for GLP-1s that are covered for the treatment of diabetes. Typical off-label drugs prescibed for weight loss and their details are listed in the Appendix in Table 3: Typical off-label drugs used as AOMs.

Bariatric surgery

UMP covers bariatric surgeries, though this coverage does not currently include a requirement to also participate in a lifestyle intervention program. The average weight loss results for bariatric surgery are slightly higher than GLP-1s, and it has a similar effect on glycemic control.[32] These outcomes also include reductions in risk of comorbid conditions that accompany weight reductions of greater than five percent found with GLP-1s.[33] Additionally, 60 to 80 percent of patients experience reductions in type 2 diabetes symptoms within one year, often resulting in medication deprescribing and in some instances diabetes remission.[34] Bariatric surgery is currently covered by many commercial health plans and Medicaid if the patient meets PA criteria.

[31] This range comes from a compilation of the clinical data on the complete list.
[32] Weight loss between glucagon-like peptide-1 receptor agonists and bariatric surgery in adults with obesity: A systematic review and meta-analysis - PubMed (nih.gov)
[33] Bariatric surgery - Mayo Clinic
[34] Bariatric Surgery and Diabetes Reversal | UPMC

Bariatric surgery carries typical risks of abdominal surgery with additional risks in long term GI side effects, and possible need for a revision surgery. Side effects of bariatric surgery, may include bleeding, infection, operational site leaking, diarrhea, and blood clots. Follow-up interventions, surgery, and hospitalizations occur in one-third of patiens within five years. Rarely, surgery-related problems can lead to death.[35] Long term side effects of malabsorption, anemia, and osteoperosis can also occur post-op along with post operative risks of stricrtures and hernias.[36]

In most clinical studies, weight loss of greater than 50 percent of excess weight between one and two years post-surgery is considered successful.[37] Many people experience steady weight loss for the first two years, then stall or regain some weight. Usually, the weight regained is less than 25 percent of the patient's total weight lost after surgical intervention.[38] Most often, bariatric surgeries are a one-time surgical procedure with a single episode of care as a claims expense while AOMs can be a lifelong expense.

The Health Technology Clincal Committee (HTCC)[39] is a statewide committee established by law in 2006 with members appointed by the HCA director. The committee includes a group of clinicians and industry experts who systematically evaluate selected health technologies for evidence-based, best practices to use in Medicaid, PEBB, SEBB, and LNI health coverage. The HTCC recently re-reviewed bariatric surgery and decided to expand coverage of additional bariatric surgery options as a result of the re-review.

Lifestyle interventions

Long-term weight loss requires a person to make dietary, activity, and cognitive changes around habits, food choices, and daily routines. Lifestyle interventions related to managing obesity involve educational elements and wholistic treatment utilizing behavioral therapy and resources to support habit change to help modify ingrained behaviors around diet, emotional eating, and physical activity. Behavioral interventions center around changing habits and reactions around food and activity and are key to the success of lifestyle interventions, particularly regarding long-term success.[40] They offer the following services: modifying and monitoring food intake, modifying physical activity, and controlling cues and stimuli that trigger eating and overeating.[41] The US Preventive Services Task Force (USPSTF) recommends offering adults with a BMI ≥30 kg/m^2 "intensive, multicomponent, behavioral interventions to achieve and maintain weight loss."[42] Adherence to dietary and activity level changes are vital to maintaining weight loss especially after goals have been met.[43] Although lifestyle interventions alone have not been demonstrated to achieve long term clinically meaningful weight loss, they can be combined with other

[35] Weight-loss Surgery Side Effects - NIDDK (nih.gov)
[36] Ibid.
[37] Bariatric (Weight Loss) Surgery: Types & Requirements (clevelandclinic.org)
[38] Ibid.
[39] Health Technology Clinical Committee | Washington State Health Care Authority
[40] Role of Behavioral Interventions in the Management of Obesity - PMC
[41] Ibid.
[42] U.S. Preventive Services Task Force Recommends Behavioral Weight Loss Interventions to Prevent Obesity-Related Morbidity and Mortality in Adults (uspreventiveservicestaskforce.org)
[43] Physical Activity and Weight Loss Maintenance - StatPearls - NCBI Bookshelf (nih.gov)

obesity treatments to encourage the best outcomes and increase the likelihood of avoiding as much weight regain after discontinuation (where relevant).[44] [45]

Plan-sponsored lifestyle interventions for weight management are an option in the marketplace. These could include coaching services on weight management, healthy eating, behavioral health solutions for weight management, and biometric monitoring. UMP currently offers lifestyle interventions through Omada for prediabetes that members may already qualify for. Some vendors can be found in the Appendix in

[44] Lifestyle and Pharmacologic Management Before and After Bariatric Surgery - PMC (nih.gov)
[45] Combined GLP-1 medication and virtual coaching leads to sustained weight loss | Cleveland Clinic Journal of Medicine (ccjm.org)

Table 4: Obesity lifestyle third-party vendors, but an exhaustive list is difficult to provide as this market is growing quickly and any list would be immediately outdated.

AOMs and health insurance

Today, two-thirds of private insurance plans[46] (including PEBB and SEBB plans) and CMS[47] restrict the prescribing of AOMs for their covered lives. A large contributing factor to these bans is the history of drug development around AOMs and their dangerous side effects. Modern treatment of obesity with AOMs[48] began with three classes of medications: thyroid hormones (1893-1960s), dinitrophenol (1931-1938; 1981-1986), and amphetamines (1932-1968).[49]

The obesity epidemic dramatically increased toward the end of the 20th century. Our greater understanding of weight-related comorbidities further increased the demand for medical obesity treatments and called for more innovation in the field. Many attempts at treating obesity with pharmaceutical intervention have been attempted and withdrawn from use given their dangerous side effects. A list with examples of these treatments and their discontinuation reasons can be found in Table 1: Prior medical obesity treatments and their discontinuation reasonsthe Appendix. Some medications had limited success in addressing obesity, but side effects and the habit-forming nature of stimulants blunted the value of their efficacy. Many efforts were made to combine different actions in AOMs to improve their efficacy and reduce side effects.[50] Many of the AOMs developed in the past also predated studies that included the behavioral health component of treating obesity. This oversight has been addressed in some later combinations, like those that combine anti-depressants like bupropion with other obesity treatments.

The second reason many payors restrict coverage of AOMs has to do with our developing clinical understanding of obesity. The AMA did not declare obesity a disease until 2013, and that decision was met with both support and surprise in the medical community.[51] Prior to the medical definition of obesity as a disease, it was considered an issue of self-control, and weight loss was considered more cosmetic than critical for preventing dangerous health outcomes. As attitudes about obesity as a health risk emerged, advances in surgical treatments offered a more reliable option than AOMs. Bariatric surgery offered additional reasons to restrict access to AOMs as it had more consistent long term weight loss with fewer side effects in most cases than pre-GLP-1 FDA-approved AOMs.[52]

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[46] Employer coverage for weight-loss drugs rises sharply, survey finds | Reuters

[47] Medicare Part D Manual (cms.gov)

[48] At the time these drugs were created, they were considered weight loss drugs, not AOMs. Obesity treatment as a medical imperative instead of a vanity exercise occurred much later. The connection between BMI and health was made in 1942 by a The Metropolitan Life Insurance Company's actuaries, but the AMA did not declare obesity a disease state until 2013.

[49] An Historical Review of Steps and Missteps in the Discovery of Anti-Obesity Drugs - Endotext - NCBI Bookshelf (nih.gov)

[50] The most notable combination in the public consciousness would be the appetite suppressant fenfluramine/dexfenfluramine plus phentermine, commonly marketed under the name Fen-Phen. This drug was eventually recalled because it caused heart valve abnormalities in up to one-third of patients. How Fen-Phen, A Diet 'Miracle,' Rose and Fell - The New York Times (nytimes.com)

[51] Is Obesity A Disease or A Behavior Abnormality? Did the AMA Get It Right? - PMC (nih.gov)

[52] What Is Best for Weight Loss? A Comparative Review of the Safety and Efficacy of Bariatric Surgery Versus Glucagon-Like Peptide-1 Analogue - PMC (nih.gov)

Why the public conversation is changing around AOMs

The launch of GLP-1s for the treatment of obesity in 2021 has been described as a new era in the treatment of obesity. It is anticipated that by 2030, nearly half of U.S. adults will have obesity, including the nearly one in four who will have severe obesity (BMI≥35 kg/m^2).[53] With a potential market this vast, and the common experience of most individuals who are overweight finding it hard to lose weight, a pharmaceutical intervention seems to be a viable option for some people.

The results observed in GLP-1 obesity clinical trials have shown higher efficacy than other non-surgical interventions. They have been found to be slightly less effective in reducing obesity than bariatric surgery but are also less invasive. Our developing understanding of obesity, the effects of GLP-1s, their costs, and AOM health insurance exclusions has fueled the public debate around coveringAOMs.

Manufacturers of these drugs expect large revenue streams and have invested heavily in them for long term business strategies. This is evidenced beyond the marketing campaigns, pipleine of related drugs, and subsequent clinical trials identifying GLP-1s as a treatment for a host of obesity-related comorbid conditions. Drug manufacturers are working GLP-1s into development of new corporate assets.[54] The manufacturer's confidence in long term utilization of GLP-1s for obesity and other comorbid conditions is strong, even as plans across the country compare the benefits of GLP-1 coverage with the dramatic increasing plan liabilities and member premiums to unsustainable levels.

Trends in AOM coverage by public entities

Coverage of GLP-1s continues to evolve. Many states and employers currently offer coverage of at least some GLP-1s for the treatment of diabetes. Coverage of GLP-1s for obesity is developing, but more slowly. As of August 2024, at least 16 states provide coverage of GLP-1s to state employees for the treatment of obesity.[55] These include Alaska, Connecticut, Delaware, Georgia, Idaho, Illinois, Indiana, Kansas, Kentucky, Massachusetts, Michigan, New Jersey, New Mexico, New York, Tennessee, and Wyoming. Further, 13 states provide coverage of GLP-1s for obesity to Medicaid recipients. Some of these cover GLP-1s with varying degrees of utilization management. Mississippi started coverage expecting significant financial impacts that did not materialize due to their utilization management planning and the higher federal rebates Medicaid receives.

A number of employers and states initiated and then rescinded coverage of GLP-1s for obesity citing financial sustainability concerns. These include the University of Texas System (~750,000 members),[56] and the state of North Carolina.[57] University of Texas analyses showed annualized costs for GLP-1s increased from approximately $18 million to over $60 million in 2023. University of Texas officials noted these GLP-1s represented a greater expense than costly drugs used to treat conditions such as cancer.[58] According

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[53] News: By 2030, nearly half of all U.S.... (The Los Angeles Times) - Behind the headlines - NLM (nih.gov)

[54] Novo Nordisk (Wegovy manufacturer) recently announceed construction of a $4.1B manufacturing facility in North Carolina to help manufacture injectible AOMs and Eli Lilly announced it plans to invest an additional $5.3B in manufacturing capabilities to produce components of its AOMs. News Details (novonordisk.com), Eli Lilly invests to increase Mounjaro, Zepbound supply (cnbc.com)

[55] Obesity Coverage Nexus - Interactive Platform (leveragegc.com)

[56] University of Texas dropping weight loss drug coverage for employees (beckerspayer.com)

[57] Some Employers Will Stop Covering Weight-Loss Drugs Due to the Cost - Business Insider

[58] University of Texas dropping weight loss drug coverage for employees (beckerspayer.com)

to plan officials in North Carolina, the plan spending on GLP-1s was estimated at $102 million in 2023, roughly 10 percent of its total drug expense.

Some states and employers have chosen to wait to offer coverage of GLP-1s for obesity. Reasons to delay coverage of GLP-1s for obesity are numerous and varied. They include waiting to gain more detailed analyses of the cost implications and to allow for more potential long-term complications data to emerge.

Strategies for AOM coverage

Strategy categories

If GLP-1s are covered for obesity, it is recommended that other FDA-approved AOMs that are not GLP-1s also be covered as they are lower cost options to achieve the same goal. Existing marketplace strategies for prescribing GLP-1s to treat obesity center around four primary areas

Strategies for covering AOMs

Strategy type	Description	Examples	Key benefits	Key drawback(s)	Implementable in UMP?
PAs and concurrent requirements	Use PAs to ensure that members who do not meet criteria are not receiving the medication	Mississippi Medicaid Program had success with this as a cost control measure	Reduces risks to those who do not meet criteria and need is determined clinically Reduces spending	Administrative burden on providers Additional PA costs	Yes
Third-party vendors who prescribe AOMs	Procuring a vendor who applies current best practice to treating obesity	Virda Health Wondr Health Noom	Heavy monitoring Performance guarantees	Additional costs for each utilizing member above the cost of the drug Full procurement	Yes
Alternative drug procurement sources	Payor finds another source for the drug	Compounding pharmacies, direct contracting with manufacturers	Lower costs per unit	Full procurement Contracting negotiations with manufacturers	No
Lifetime maximums	Payor limits the time or dollar amount for using GLP-1s	Britain's National Health Service (NHS): 2 years[59] Mayo Clinic employees: $20K lifetime Rx maximum[60]	Maximum cost is definite	No clinical basis for any restriction of access	Not recommended, but possible

[59] Obesity - Treatment - NHS (www.nhs.uk)
[60] Mayo to launch weight loss drug telehealth service (beckershospitalreview.com)

Strategies that could be implemented in UMP

Use of PAs and concurrent requirements

Payors have explored many different PA strategies to ensure that GLP-1s are prescribed in a cost-effective and clinically appropriate manner. Prioritizing both goals is how we can control the cost of covering GLP-1s without restricting access to members who meet medical necessity. PAs involve plan approval for coverage of specific services, supplies, or prescription drugs before they are provided to the member. They are used to ensure that necessary steps are taken by the member and the provider before the prescription will be covered. This is standard practice for high cost and high-risk drugs. Many of the commercial and Medicaid plans that have implemented GLP-1 coverage for obesity have found success with various PA strategies, while other strategies have not had the planned effect on plan spend and member utilization goals. An effective PA program could help ensure GLP-1s are not prescribed unless the member meets clinical criteria indicating obesity and/or associated chronic health conditions exacerbated by obesity, other weight management methods are ineffective to help patients achieve or sustain weight loss, and that patients are maintaining lifestyle intervention treatment plans as well.

Clinically, PA impacts largely depend on the construction and administration of the PA. There is potential for reduced access to GLP-1s since members may be required to try alternative obesity treatments and have access to GLP-1s only in situations in which alternative obesity treatments are ineffective at achieving weight loss. There is also a potential for members treating their obesity with less costly AOMs with fewer side effects in their step therapies and never needing GLP-1 prescriptions. When determining the particular elements of any PA, we would recommend allowing clinical experts at HCA to work with our third-party administrators during the implementation stages to ensure that the most up-to-date research is used in crafting them. As has been noted above, treatment of obesity with GLP-1s is a new area and payors and providers are still striving to determine best practice.

Implementing a PA program for GLP-1s through our existing PBM should occur in our usual benefit change process, the requests for renewal (RFRs) which takes approximately one year. The only concerns around health equity with this option would be that the process itself not be any more burdensome to the member than any other PA.

PAs for GLP-1s center around customizing both the content and the cadence of the PA to best ensure that overprescribing and waste are minimized without restricting necessary access. At this time, no provable, consistent best practice has emerged around either criterion.

PA cadence options

The cadence of the PAs for AOMs in general and GLP-1s in particular is critical to ensure efficacy and adherence as well as reducing the impact of dangerous side effects and plan waste. Many drug PAs are approved for a 12-month duration with reauthorizations required every 12 months. But we've seen more success for payors who have an initial reauthorization early in GLP-1 treatment (between two and six months) and a regular cadence of reauthorizations after that. The state of Mississippi's Medicaid program presented to other Medicaid payors at a Milliman conference in July of 2024 that their PA program, which included an initial reauthorization at three to six months, contributed to GLP-1 costs substantially below what they projected.

The more frequent PAs do have an additional cost, as the rough cost for each filed PA is approximately $50 per PA, but their intent is to ensure that our overall GLP-1 spend minimizes waste and that negative side effects are addressed early.

PA content options

The content of PAs centers around four key areas:

BMI thresholds

For AOMs, suggested PA criteria may include that the member meets age requirements per FDA indication and has a BMI greater than or equal to 30 kg/m^2 or has a BMI greater than or equal to 27 kg/m^2 with at least one weight-related comorbid condition. If an AOM is FDA approved for use in pediatric patients (age 12-17), the pediatric patient must have an initial BMI at the 95^{th} percentile or greater for age and sex to qualify for coverage.

Step therapies

Non-GLP-1 AOMs are approved by the FDA (i.e. phentermine/topiramate and bupropion/naltrexone). These AOMs are significantly less expensive than GLP-1s and can be an effective option for members seeking to address obesity. Therefore, it may be appropriate to require trial of non-GLP-1 AOMs prior to allowing coverage of GLP-1s, unless contraindicated or not tolerated.

Lifestyle program requirements

Lifestyle interventions for GLP-1s can be required prior to prescription as part of a step therapy, concurrent with starting GLP-1s, and/or after treatment has concluded to reduce weight regain. These interventions include diet therapy, exercise, and behavior modification. One Danish study indicated that concurrent lifestyle interventions with liraglutide (generic for GLP-1, Saxenda) treatment maintained at least 10 percent greater weight loss results than those who received the placebo and lifestyle interventions.[61] These lifestyle interventions can either be administered independently by UMP or via a procured third-party vendor. Members of UMP with obesity would already have access to the Omada diabetes prevention program, as most members without diabetes who meet criteria for AOMs designated by the FDA meet Omada's eligibility criteria as established by the CDC. Participation could be measured during regular PAs that occur after the initial PA is approved. Participation may be considered met if the member connects with their health coach a minimum number of times per month, uses connected devices to show tracking of weight and/or movement, completion of resource modules, or other engagement metrics as available through the solution.

Exploration of alternative treatment options

Another criterion that could be added to PA requirements is requiring the provider to discuss the outcomes of all non-pharmaceutical interventions available to the member, including bariatric surgery.

[61] Healthy weight loss maintenance with exercise, GLP-1 receptor agonist, or both combined followed by one year without treatment: a post-treatment analysis of a randomised placebo-controlled trial - eClinicalMedicine (thelancet.com)

Key benefits and concerns about a PA strategy for AOM prescribing

Benefits	Concerns
• Straightforward implementation • Customizable • Fewer additional costs are incurred per member than with a vendor • UMP is in control of additional costs above prescription cost through the PA cadence and structure • UMP can direct members to preferred products with the lowest net cost • Ensures necessary step therapies are performed before GLP-1 treatment	• UMP assumes all financial risk • Restricts access (but not more than other PAs) • Potential for more GLP-1 prescriptions/year than a vendor-based solution • Additional administrative burden on Washington's providers • Less oversight by payor on lifestyle interventions and use

Procurement of a third-party vendor

Vendors providing AOM prescribing as part of obesity treatment use a variety of strategies intended to control GLP-1 prescribing costs without restricting necessary access to medications based on criteria determined between the vendor and the payor. Their primary stated advantage is that they offer integrated care-coordination between lifestyle interventions and medical interventions. The vendor could provide lifestyle intervention as a requirement of coverage of GLP-1s or could manage both the medical and lifestyle interventions for the payor. Lifestyle intervention programs could also be made available to members who are or have undergone bariatric surgery or are looking for a non-medical path to building new habits and losing weight, creating a more wholistic approach to treating obesity in UMP.

The vendor may use the biometrics and data from the lifestyle interventions along with historical claims data to tailor the medical obesity treatment and the prescribing of AOMs would be managed by the vendor care team, often including obesity medicine specialists. These programs self-report better ROIs than strategies where the lifestyle intervention and prescribing are handled by payors directly. But those downstream savings have been self-reported from vendors and would require third-party verification. Some of these vendors offer performance guarantees around member success in their programs, costs of prescription drugs, deprescribing with success of lifestyle interventions, or member engagement, which may mitigate from some risks for UMP found in a self-administered strategy. There are, however, additional costs. The overall annual cost to treat one individual with obesity with a GLP-1 through a vendor is higher than simply covering the medications alone. The vendors assert that these additional costs will be less than the savings created by their methods that minimize prescribing costs, but these claims have not yet been suitably verified by an impartial third party.

Vendor-based solutions have differing paths toward success and best practice would be to obtain a full survey of these vendors in an RFI and use that information to shape an RFP. Examples of available options from vendors who have marketed their products to ERB in the past include:

- Incentivizing use of lifestyle interventions and adherence to programs.
- Algorithm based analyses of claims data to find most likely candidates and maximize treatment success.

    - Some vendors also offer the possibility of using this data to find members who would benefit from earlier interventions and offering those to avoid the member from needing downstream GLP-1 prescribing.
- Built-in step therapies and PA processes with customizable paths.
- In-house medication review management to ensure clinical efficacy and cost containment.
- Behavioral health resources included to address this aspect of obesity treatment.
- Diet and metabolic education elements.
- Side-effect management.
- Health coaching.
- Prescribing and deprescribing closely monitored to ensure best practices and mitigate waste.
- Performance guarantees for risk mitigation.
- Varied billing options: PMPM, PPPM,[62] preventative-care claims billing.

Third-party vendors offer a potentially increased clinical benefit of weight loss and reduced risks of dangerous side effects, but outcomes are dependent on how much support was provided to members to help manage lifestyle interventions and side effects. There is also a potentially restricted benefit to members because the additional steps to enroll and continue in the vendor solution program may prevent some members from starting or continuing the use of this medication.

There are two key concerns for utilizing this method. The first is that the only covered access for GLP-1s for members would be through the vendor and drugs would be limited to the options the vendor makes available, possibly limiting the list of drugs available to the members. The members could not have prescriptions written by their own providers. Providers who believe members would benefit from AOM treatment would need to refer the member to the vendor for access. This rigidity is how the vendors maintain their commitment to controlling costs. The second major criticism of third-party vendors is that if AOMs are prescribed over a member's lifetime, then each member who uses the medication is costing the payor both the cost of the medication and the cost of the prescribing program ensuring a higher cost per utilizing member.

Adopting a solution via a vendor also has implementation concerns. This likely could have an implementation timeline of a minimum of three years once funded to perform a full procurement for a new vendor. The additional year is accounted for because procuring a new solution requires more initial steps than described for the PA implementation. An RFI is recommended given the lack of established clinical best practice in the treatment area. A Request for Proposals (RFPs) would then be initiated and evaluated in the marketplace to fulfill procurement requirements and ensure that we select the best possible vendor for UMP. Once selected, the vendor would need to go through contract negotiations, security and program administration implementation activities, and new reporting requirements drafted to complete ongoing evaluation of the selected vendor. Processes may need to be updated to coordinate efforts between the vendor, the contracted carrier, and ERB. Before rollout, communications for impacted members and providers would need to be drafted, reviewed, and sent.

[62] PMPM (per member per month) means a charge is added for every member if they use the benefit or not. PPPM (per participant per month) means that an additional charge is added only for members who use the benefit.

Key benefits and concerns about a vendor-based solution for GLP-1 prescribing

Benefits	Concerns

• Coordinated care team
• Built in step therapies help reduce GLP-1 prescribing
• Performance guarantees insulate some financial risk
• Individualized treatment plans
• Customizable
• Avoids universal approach to utilization management
• Provides better oversight in adherence to interventions
• Better access to specialists in obesity medicine for treatment
• May offer success to higher risk patients who would fail on a less rigorous intervention with GLP-1 prescribing
• Ensures equity of access to best practice for obesity health regardless of income
• Burden of best practice determination and continual research is on vendor
• Potential to reduce number of GLP-1 prescriptions compared to PA alone
	• Additional cost incurred for every member above the drug cost
	• Members cannot get prescriptions from their own provider(s)
	• Touted downstream ROIs are vendor reported and require third-party validation
	• Will require a full procurement
	  ○ Takes three years minimum to implement
	  ○ More up-front costs (RFI, RFP, contract negotiations, implementation costs for some programs)
	  ○ More ongoing operational costs above fees from vendor (internal contract management)

Strategies removed from consideration

Prescribing AOMs without PAs

A full analysis of this strategy has been completed in the prior section Impacts of coverage without Prior Authorization (PA) for comparison to the recommended PA strategy. Not utilizing PAs was found to cost UMP more than double the projected costs of using the recommended PA strategy and carries additional clinical and policy risks around overutilization and access to the medication when there is no medical necessity.

Compounding pharmacies as alternative suppliers

Compounding pharmacies mix raw materials and ingredients of drugs for patients for two reasons:

- To create customized, patient-specific prescriptions that may differ in strength, dosage form, or other characteristics from drugs that come from the manufacturer.
- To fill supply gaps during drug shortages.

Over the last three years, there has been a rise in compounding pharmacies offering to make compounded semaglutide and tirzepatide (GLP-1) prescriptions. Typically, compounding pharmacies are not able to produce compound prescriptions for commercially available drugs that are approved by the FDA. However, in the event of a drug shortage, compounding pharmacies may be able to use bulk ingredients to help prevent patient access issues.[63]

One of the concerns about procuring drugs through compounding pharmacies is the source of the drug ingredient. Eli Lilly, the manufacturer of tirzepatide, released a letter in June 2024 citing, "Lilly is the only lawful supplier of FDA-approved tirzepatide medicines—Mounjaro and Zepbound—and does not provide tirzepatide (the active ingredient in Mounjaro and Zepbound) to compounding pharmacies, med-spas, wellness centers, online retailers, or other manufacturers."[64] Given that Eli Lilly has not authorized tirzepatide to be sold or used in compounding pharmacies, it is assumed that the actual drug ingredients used by compounding pharmacies may be semaglutide salts or tirzepatide salts (or drug ingredients with similar properties to the FDA-approved versions). These salts are produced by other manufacturers and are typically reserved for research purposes. Given that these are not FDA-approved versions of the drugs, they are not under the purview of FDA safety standards, unlike ingredients used by compounding pharmacies for other prescriptions.

Additionally, the FDA only allows compounding pharmacies to make compounded versions of FDA-approved drugs that are not commercially available, including during times of drug shortages. Once a drug shortage is resolved, the FDA disallows ongoing reliance of compounded version for filling prescriptions. This option could not be available long term, and therefore acquiring GLP-1s through compounding pharmacies would be unreliable.

[63] Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss | FDA
[64] An Open Letter From Eli Lilly and Company Regarding Certain Practices Related to Mounjaro® and Zepbound® | Eli Lilly and Company

Due to these concerns, HCA does not recommend compounding pharmacies as a safe, effective, or reliable option for procuring lower-cost GLP-1s as a method to balance overall plan costs and establish plan coverage.

Direct contracting with manufacturers

Another option to pursue lower pricing for these medications is direct contracting with the manufacturers. Agreements would often require brand-exclusivity and would not offer the full portfolio of GLP-1s available in the market.

There are already some elements of this in the marketplace. Eli Lilly launched a direct-to-consumer purchasing option for their AOM, tirzepatide (Zepbound), along with other medications used to treat endocrine disfunction. The LilyDirect price is reduced to a per-month cost of $399 (a 62 percent price reduction from retail) on a monthly dose without an autoinjector.[65] If this method is successful, more manufacturers may add options for direct-to-consumer sales in the future which could open more options on price flexibility and the ability to negotiate with manufacturers.

Direct contracting with a drug manufacturer comes with significant administrative burdens. Two options for direct contracting exist; HCA could either:

- Directly procure a contract with a manufacturer, or
- Rely on existing third-party administrators to enter into agreements with these vendors to administer services to the UMP population.

Completing a competitive procurement at HCA has a long timeline and large administrative burden in addition to the contract negotiations, implementation tasks, and ongoing account management oversight. HCA's third-party administrators are not contractually required to enter into these agreements and could deny HCA's requests to participate with these vendors. Additionally, separate agreements with direct-to-consumer vendors may put rebates at risk if they violate current rebate agreements. Finally, third-party administrators may assess implementation and ongoing fees to provide oversight and administration of these agreements. It is unknown what financial impacts this may have to the UMP benefits. Due to unknown costs, no available references for these companies and their ability to meet program and member needs, and the large administrative burden to UMP and carriers, this is not currently a viable option.

Maximum lifetime treatment allowance for pharmaceutical obesity treatment

Lifetime maximums have been an attractive strategy for GLP-1 prescribing in the marketplace. They offer the most predictable cost estimates as an absolute maximum cost for a population can be calculated. This resolves one of the largest, cost-based risks around chronic use of GLP-1s. Maximums in this space can be defined in one of two ways, maximum length of treatment or maximum lifetime dollar amount on prescriptions. Examples of both are given in the chart above, Strategy categories. NHS's two-years lifetime and Mayo's $20K lifetime were on the more generous side. Shorter maximums also exist in the market.

[65] Patients receive vials of medication and inject with traditional syringe.

Wyoming covered AOMs for six months in the member's lifetime prior to the launch of GLP-1s for obesity and has since applied this lifetime maximum to GLP-1s.

There is no consistent agreement around a clinical best practice for a finite length of maximum treatment with GLP-1s. There currently is no identified optimal length of treatment for obesity as such treatment can be highly individualized. This also creates an inequity of treatment as individuals with higher BMIs may not have enough time within the limitations of the maximum to address their health risks while someone with a BMI closer to 30 kg/m^2 could achieve a healthy BMI in the same time frame. Maximums could have reduced long-term clinical benefits on obesity as studies indicate stopping the medication usually results in regaining some of the lost weight. This undercuts the greatest benefit of treating obesity, reducing your risks for comorbid conditions, as the risks will increase again with the regained weight.

Given these clinical challenges, the workgroup recommends not implementing a strategy around lifetime maximums until there is an evidence-based, clinically verified, best practice established around maximum treatment times and how to reduce subsequent weight regain after drugs are discontinued.

Final summary

Recommendation

If UMP is authorized to cover GLP-1s to treat obesity, it is recommended that UMP:

1. Remove language prohibiting the prescribing of AOMs from UMP plans.
2. Set up customized PA strategies for AOMs using the above PA content and cadence and making necessary adjustments as additional best practices emerge.
3. Continue to review utilization, market trends, and strategy innovations to ensure the benefit is managed efficiently.
4. Enhance this coverage by procuring a third-party vendor to address obesity in members who do not meet PA criteria.

If this coverage is approved in the 2025–2027 operating budget, the earliest date UMP members could have access to this benefit would be January 1, 2027.

Important outstanding questions

When designing a strategy for AOM prescribing, there are still many unanswered questions about the clinical application of GLP-1s and other AOMs. HCA's clinical staff recommend having answers to these questions to best design an AOM prescribing strategy for UMP, but these questions are yet to be addressed by the medical community.

- Which subpopulations of individuals are most successful in long-term obesity treatment with GLP-1s?
- What are the impacts of side effects and how often do those side effects lead to stopping GLP-1s outside of clinical trials?
- How should the use of GLP-1s be coordinated with bariatric surgery? (Prior to surgery? As an adjunct to surgery? For use if surgery is ineffective at long-term treatment of obesity?)
- What is the long-term efficacy of AOMs once patients discontinue use?

Final thoughts

This report is limited in scope to UMP's coverage options for GLP-1 prescribing for obesity and a coverage recommendation. This report does not address the advisability of implementing GLP-1 coverage for obesity. Treating obesity is important for the health of our populations. Strategies for treatment need to be approached with thoughtfulness and intention to ensure our members' best health outcomes and to be good stewards of state funds. There is no easy answer that guarantees success and what is provided here is our best analysis of the marketplace. As more information about and experience with GLP-1s for treatment of obesity emerges, this analysis could be further refined. Due to the significant clinical and fiscal impacts of GLP-1 treatment for obesity, it is important the plans to utilize them be well-constructed and carefully implemented.

Works consulted

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- Bariatric surgery | Mayo Clinic
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- Bariatric (Weight Loss) Surgery: Types & Requirements | Cleveland Clinic (clevelandclinic.org)
- Combined GLP-1 medication and virtual coaching leads to sustained weight loss | Cleveland Clinic Journal of Medicine (ccjm.org)
- Consequences of Obesity | Overweight & Obesity | CDC
- Diabetes and African Americans | Office of Minority Health (hhs.gov)
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- Racial and Ethnic Disparities in Adult Obesity in the United States: CDC's Tracking to Inform State and Local Action | CDC
- Role of Behavioral Interventions in the Management of Obesity - PMC
- Some Employers Will Stop Covering Weight-Loss Drugs Due to the Cost | Business Insider
- Special Report: Potential Strategies for Addressing GLP-1 and Dual GLP-1/GIP Receptor Agonist Shortages | PMC (nih.gov)
- These 16 states cover weight loss drugs for their employees (beckerspayer.com)
- U.S. Preventive Services Task Force Recommends Behavioral Weight Loss Interventions to Prevent Obesity-Related Morbidity and Mortality in Adults (uspreventiveservicestaskforce.org)
- University of Texas dropping weight loss drug coverage for employees | Beckers Healthcare (beckerspayer.com)
- Wealth by Race of Householder | US Census Bureau (census.gov)
- Weight loss between glucagon-like peptide-1 receptor agonists and bariatric surgery in adults with obesity: A systematic review and meta-analysis | PubMed (nih.gov)
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- Weight regain and cardiometabolic effects after withdrawal of semaglutide: The STEP 1 trial extension - Wilding - 2022 - Diabetes, Obesity and Metabolism | Wiley Online Library
- What Is Best for Weight Loss? A Comparative Review of the Safety and Efficacy of Bariatric Surgery Versus Glucagon-Like Peptide-1 Analogue | PMC (nih.gov)

Appendix

Table 1: Prior medical obesity treatments and their discontinuation reasons[66]

Year	Drug	Alleged mechanism	Reason(s) for discontinuation
1892	Thyroid	Thermogenesis	Hyperthyroidism
1932	Dinitrophenol	Thermogenesis	Disapproved due to cataracts/neuropathy
1937	Amphetamine	Sympathomimetic	Disapproved due to addiction
1961-1990	Human chorionic gonadotropin	Reduce food intake	Disapproved; ineffective compared to placebo
1971	Aminorex	Sympathomimetic	Withdrawn after marketing due to pulmonary hypertension
1985	Gelatin-based very low-calorie diet	Reduce food intake	Cardiovascular deaths
1991-1995	Fluoxetine	Serotonin reuptake inhibitor	Weight regain after loss
1985-1998	β-3 Agonists	Increased thermogenesis	Limited effect; increased HR
1997	Fenfluramine	Serotonergic receptor activation (5HT2c)	Withdrawn after marketing due to cardiac valvopathy and pulmonary hypertension
1998	Phenylpropanolamine	Sympathomimetic	Withdrawn after marketing for causing strokes
1999	Leptin	Leptin receptor agonist-reduced food intake	Limited weight loss
2003	Ephedrine/Caffeine & Herbal Ma Huang	Sympathomimetic and adrenergic blocker	Withdrawn after marketing for heart attacks/stroke
2007	MK-0557	Neuropeptide Y5 (NPY) receptor antagonist-reduced food intake.	Limited effectiveness
2007	Ecopipam	D2/D5 agonist-reduce food intake	Suicidality

[66] An Historical Review of Steps and Missteps in the Discovery of Anti-Obesity Drugs - Endotext - NCBI Bookshelf (nih.gov)

Year	Drug	Alleged mechanism	Reason(s) for discontinuation
2008	Tesofensine	Triple Monoamine Reuptake Inhibitor	Raised blood pressure
2009	Melanocortin-4 Receptor Agonist	Reduce Food Intake	Limited effectiveness, priapism
2010	Capsinoids	Thermogenesis	Limited effectiveness
2010	Rimonabant	Endocannabinoid agonist	Suicidality
2011	Sibutramine	Triple Reuptake Inhibitor	Withdrawn after marketing for cardiovascular toxicity
2020	Lorcaserin	Serotonergic Reduce Food Intake	Cancer

Table 2: FDA-approved AOMs

Generic name and delivery method	Retail name(s)	Patient age	Drug type(s)	Expected weight loss	Estimated cost/month[67]
Benzphetamine (Oral)	Brand name no longer available	≥17	Stimulant/appetite suppressant	3.3 kg in 16 weeks	$101.63
Diethylpropion (Oral)	Brand name no longer available	≥17	Appetite suppressant	5-10 lbs in 1 month	$108.04
Liraglutide (1x day subcutaneous injection)	Saxenda	≥12	GLP-1	4.8 percent in 56 Weeks	$1,430
Naltrexone-bupropion (Oral)	Contrave	≥18	Addiction treatment; Anti-depressant	5.4 percent in 56 weeks	$667.84
Benzphetamine (Oral)	Brand name no longer available	≥17	Stimulant/ appetite suppressant	3.3 kg in 16 weeks	$101.63
Diethylpropion (Oral)	Brand name no longer available	≥17	Appetite suppressant	5-10 lbs in 1 month	$108.04
Liraglutide (1x day subcutaneous injection)	Saxenda	≥12	GLP-1	4.8 percent in 56 Weeks	$1,430

[67] drugs.com or similar.

Generic name and delivery method	Retail name(s)	Patient age	Drug type(s)	Expected weight loss	Estimated cost/month[67]
Orlistat (Oral) Also Available OTC	Xenical, Alli	≥12	Lipase inhibitor	5 percent in 3 months	$803 (Xenical) $672.99 (Generic)
Phendimetrazine (Oral)	Brand name no longer available	≥17	Stimulant/ appetite suppressant	5-10 lbs in 1 month	$100.88
Phentermine (Oral)	Adipex; Suprenza	≥12	Stimulant	5 percent in 6 months	$76 (Adipex) $12.36 (generic)
Phentermine-topiramate (Oral)	Qsymia	≥12	Stimulant; Anti-epileptic	10 percent in 2 years	$211
Semaglutide (1x weekly subcutaneous injection)	Wegovy	≥12	GLP-1	15 percent (time not specified)	$1,430
Setmelanotide68 (Subcutaneous injection schedule)	Imcivree	≥6 (With specific diagnoses)	Melanocortin-4 agonist	0.6 kg per week	$3,623.40
Tirzepatide (1x weekly subcutaneous injection)	Zepbound	≥18	GLP-1	18 percent (time not specified) 69	$1,06070
Diethylpropion (Oral)	Brand name no longer available	≥17	Appetite suppressant	5-10 lbs in 1 month	$108.04
Liraglutide (1x day subcutaneous injection) **This medication should have a generic launching in 2024**	Saxenda	≥12	GLP-1	4.8 percent in 56 Weeks	$1,430

[68] This drug is not an alternative to GLP-1s and is used to treat weight gain caused by specific, rare genetic conditions.
[69] FDA Approves Most Potent Weight Loss Drug Yet | TIME
[70] Very newly approved, not available on drugs.com. Zepbound (Tirzepatide) for Weight Loss: Learn About the Cost - GoodRx

Table 3: Typical off-label drugs used as AOMs

Generic name and delivery method	Retail name(s)	Primary use	Expected weight loss	Common side effects	Rare but serious possible side effects	Treatment time range	Estimated cost/month[71]
Bupropion	Wellbutrin	Anti-depressant, smoking cessation	3-5 percent more weight loss than placebo in 24 weeks	Dry mouth, GI upset, rapid heartrate, agitation, weight loss	Anxiety, Panic attacks, Seizures, manic episodes	Long term	$17
Metformin	Fortament, Clucophag, Glumetza, Riomet	Type 2 diabetes, PCOS treatment Prediabetes, insulin resistance	In 2.8 years patients lost 2.1 kg (4.6 lbs) without lifestyle interventions and 5.6 KG (12.34 lbs) with lifestyle interventions; Metformin assisted in maintaining weight loss	Nausea, vomiting, muscle pain, dizziness,	Lactic acidosis	Long term	$11
Semaglutide	Ozempic	Type 2 diabetes treatment (GLP-1 agonist)	3.5 more KG lost than placebo group	Low blood sugar, GI upset	Thyroid cancer, pancreatitis, gallbladder problems, kidney problems, severe GI upset, stomach paralysis	Long term	$1029.35
Pramlintide	SymlinPen	Type 1 and 2 diabetes (used after other medications) (Amlyn analog)	40 percent of study participants lost ≥ 10 percent of body weight (study included lifestyle interventions)	Nausea, vomiting, loss of appetite, headache	Ongoing nausea, hypoglycemia, stomach paralysis	Long term	$1255

[71] drugs.com or similar

Generic name and delivery method	Retail name(s)	Primary use	Expected weight loss	Common side effects	Rare but serious possible side effects	Treatment time range	Estimated cost/month[71]
Dulaglutide	Trulicity (does not have an FDA-approved weight loss formulation at this time)	Type 2 diabetes; cardiac risk factors in patients with type 2 diabetes (GLP-1 agonist)	10 lbs lost in 9 months on highest dose when combined with lifestyle interventions.	Nausea, vomiting, diarrhea,	Hypoglycemia	Long term	$977.42
Zonisamide	Zonegran, Sonisade	Anticonvulsive	5 percent weight loss in 1 year when combined with lifestyle interventions	Depression, anxiety, panic attacks, insomnia, suicidal ideation, eye pain, drowsiness, dizziness, agitation, loss of coordination, loss of appetite, permanent vision loss	Seizures, skin reactions, blood cell disorders	Long term but very high risk of side effects for this drug	$35

Table 4: Obesity lifestyle third-party vendors

Vendor	Diet tracking	Exercise tracking	Educational component	Behavioral health component	Biometric monitoring	Medical weight loss with prescriptions
9AM Health	Y	Y	Y	Y	Y	Y
Abacus health solutions	Y	Y	Y	Y	Y	Y
Dario Health	Y	Y	Y	Unknown	Y	Y
Form Health	Y	Y	Y	Unknown	Y	Y
Iliant Health	Y	?	Y	Y	Y	Y
Livongo	Y	Y	Y	Unknown	Y	Y
Noom	Y	Y	Y	Y	N	Y
NourishedRx	Y	N	Y	N	N	N
Omada for Prediabetes/Weight Management	Y	Y	Y	Y	Y	N
Teledoc	Y	Y	Y	Y	Y	Y
Virda Health	Y	Y	Y	Y	Y	Y
Virta Health	Y	Y	Y	Y	Y	Y
Weight Watchers	Y	Y	Y	Y	Y	Y
Wondr	Y	Y	Y	Y	Y	Y