STATE OF NORTH CAROLINA **Department of State Treasurer** NC State Health Plan for Teachers and State Employees	**REQUEST FOR INFORMATION NO.** 270-20240419GLP Due Date: May 31, 2024, 2:00 PM ET
Refer ALL Inquiries to: Kimberly Alston, Contracting Agent	Issue Date: April 19, 2024 Commodity: 851017 Health Administration Services
E-Mail: Kimberly.Alston@nctreasurer.com with a copy to SHPContracting@nctreasurer.com	Using Agency Name: NC State Health Plan for Teachers and State Employees

MAILING INSTRUCTIONS: Respondents shall submit one (1) signed, original paper response, and one (1) electronic copy on a flash drive and one (1) redacted electronic copy on a flash drive, if applicable pursuant to Section 3.0.D. The address label shall clearly note the RFI number as shown below. It is the responsibility of the submitting entity to have the RFI in this office by the specified time and date of opening.

DELIVERY ADDRESS
RFI NO. 270-20240419GLP NC Department of State Treasurer State Health Plan Division Attn: Kimberly Alston, Contracting Agent 3200 Atlantic Avenue, Raleigh, NC 27604

NOTICE TO RESPONDENTS

Responses to this RFI will be received at the address above until May 31, 2024, 2:00 PM ET.

QUESTIONS

Email written questions no later than April 30, 2024, 5:00 PM ET to Kimberly.Alston@nctreasurer.com with a copy to SHPContracting@nctreasurer.com.

EXECUTION

RESPONDENT NAME:	E-MAIL:	
AmVentureX, Inc., dba Biocoach	michael@biocoach.io	
STREET ADDRESS:	P.O. BOX:	ZIP:
225 S 6th St., STE 2580		55402
CITY & STATE:	TELEPHONE NUMBER:	TOLL FREE TEL. NO:
Minneapolis, MN	507-269-0155	(800)587-5496
TYPE OR PRINT NAME & TITLE OF PERSON SIGNING:	FAX NUMBER:	
Michael Silverstein, chief product officer		
AUTHORIZED SIGNATURE:	DATE:	
	May 29, 2024	

1.0 EXECUTIVE SUMMARY

The North Carolina State Health Plan for Teachers and State Employees ("Plan"), a division of the North Carolina Department of State Treasurer, provides health care coverage to more than 740,000 teachers and school personnel, State Employees, retirees, current and former lawmakers, state university and community college personnel, and their dependents. The mission of the State Health Plan is to improve the health and health care of North Carolina teachers, State Employees, retirees, and their dependents, in a financially sustainable manner, thereby serving as a model to the people of North Carolina for improving their health and well-being.

2.0 PURPOSE AND OBJECTIVES OF THE REQUST FOR INFORMATION

The Plan's net spend on glucagon-like peptides (GLP-1s) and gastric inhibitory polypeptide (GIP) agonists for weight loss exceeded $100 million in 2023 and was projected to exceed $170 million in 2024. In order to limit this financially unsustainable expense, the Board of Trustees for the State Health Plan for Teachers and State Employees ended coverage of GLP-1s, GIP-GLP-1 agonists and other similar molecular entities used for weight loss as a benefit effective April 1, 2024.

The Board further directed Plan staff to explore options that may allow members who need these medications the most to obtain them, informed by medical necessity and long-term cost effectiveness, under a fiscally sustainable model, budgeted over at least the next five years. To that end, the Plan is issuing this Request for Information (RFI) to gather ideas and solutions from the marketplace.

This RFI is intended to collect information, recommendations, and potential solutions for the Plan to consider respecting the feasibility of providing benefit coverage to Plan members to use GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities, for the purpose of weight loss in a manner that is financially sustainable for the Plan.

The Plan is seeking responses outlining detailed solutions that would address the following:

A. Permit the Plan to provide benefit coverage to Plan members to use GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities, for the purpose of weight loss.

B. Establish a pricing framework that would permit the Plan to provide such benefit coverage in a fiscally responsible manner in order to maintain financial sustainability. For example, the Plan seeks the ability to:

    1. Pay for varying percentages of the unit cost according to medical necessity considerations.
    2. Receive the same effective net price if the Plan only choses to pay for a medication for an additional FDA indication without paying for it for all other indications.
    3. Audit claims, rebates, and prior authorizations for accuracy and compliance with applicable laws and regulations.

C. Potential for establishing a program outlining certain eligibility requirements, parameters, or other prerequisites for Plan members to follow in order to receive benefit coverage of GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities, for weight loss. As a result, the Plan seeks the ability to:

1. Require that an approved weight loss program or nutrition classes be completed before approval of payment for the medication.
2. Develop step therapies involving lower cost medications.
3. Require that medications be prescribed by a practitioner with appropriate levels of expertise.
4. Prohibit Body mass index (BMI) measurements from being estimated via telehealth visit to ensure accuracy and accountability, while enabling a data collection process that supports the successful implementation of the benefit.

D. Potential for establishing a program wherein the Plan has the flexibility to establish parameters for utilization management of GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities for weight loss, which may include considerations such as, but not limited to:

1. BMI;
2. Current weight;
3. Documented history of lifestyle modifications, which may include reduced calorie intake and increased physical activity;
4. Documented enrollment and measurable participation in other nutritional or dietary programs;
5. Consideration of evidence for one or more comorbid conditions or other obesity-related medical conditions;
6. Data analytics and reporting tools supporting successful claims adjudication and program evaluation;
7. Requirements for in-person treatment visits to verify efficacy of medications for individuals; or
8. Any other considerations or parameters that would support a program to achieve the Plan's objectives of serving the members who need these medications the most.

E. Provide cost, price structures, or other relevant expense information related to the recommendations and potential solutions submitted.

3.0 RFI PROCEDURES

A. Schedule

Responses must be received by the date, time and the location specified on the cover sheet of this RFI. Respondents may be requested to present and discuss their submissions at the Plan's offices in-person or remotely. If the Plan requests such a presentation, respondents will be notified of the specific date and time at least two weeks in advance of any presentation.

B. Clarification Questions

Clarification questions will be accepted until April 30, 2024, 5:00 PM ET as specified on the cover sheet of this RFI (the "Clarification Period"). All questions must be submitted in writing. Responses to all questions received shall be addressed and issued as an addendum to this RFI. During the Clarification Period, respondents are strongly encouraged to raise any and all

questions or concerns about the RFI. Any questions or concerns not raised during this period are considered waived by the respondent.

Question submittals should include a reference to the applicable RFI section and be submitted in the format shown below:

No.	Reference	Respondent Question
1.	RFI Section, Page Number	Respondent Question . . . ?

C. Response

The Plan recognizes that considerable effort will be required in preparing a response to this RFI. However, please note this is a request for information only, and not a request for services. The respondent shall bear all costs for preparing this RFI. **Under no circumstances will any documents, information, recommendations, or potential solutions submitted in response to this RFI, or any communications between the Plan and a respondent, create a binding agreement or contract, or expectation thereof, between the Plan and respondent or between the State of North Carolina and respondent.**

1. Content and Format

The Plan expects a comprehensive, detailed explanation of the workings of each component of the response. Each component of the response will explain how it will operate to address the needs and objectives of the Plan as identified in Section 2.0. The Plan is not interested in brochures or "boilerplate" responses. Instead, responses should clearly define how the proposed solution(s) would meet the Plan's needs. Any issues or exceptions to the Plan's requirements should also be identified and explained.

The response may include charts, graphs, or other visuals that assist in demonstrating how a component of a response operates or how that component would meet the Plan's objectives.

A comprehensive, detailed equipment list including software, applications and other information technology components required for the proposed solution should be provided. The Plan is not interested in participating in any field trials of new equipment or software.

The response should define all services that would be required by the proposed solution. The response should also include:

- The respondent's understanding of the project and services by addressing the Plan's objectives; and
- An estimated total cost of ownership for the solution including continued compliance with emerging industry standards.

2. Multiple Responses

Multiple responses, or alternative individual solutions will be accepted from a single respondent provided that each response is comprehensive, meets all of the Plan's requirements, and is truly unique. If submitting multiple responses, place each response in a separate envelope and clearly mark responses as "Response #1, Response #2, etc.

D. Confidentiality

Responses obtained by the Plan under this RFI and items derived therefrom are subject to the State Public Records Act, Chapter 132 of the North Carolina General Statutes (the "SPRA").

If a response contains any proprietary or confidential information protected from public disclosure under the SPRA, the respondent shall submit a redacted electronic copy on a flash drive to the Plan with its response. Any proprietary or confidential information under the SPRA must be clearly redacted by the respondent in black markings fully covering and obscuring such information within the redacted electronic copy of the RFI response. By submitting a redacted electronic copy, respondent warrants that it has a good faith opinion that the redacted information in fact meet the requirements of the SPRA and the SPRA prevents their public disclosure. Blanket assertions of confidentiality are not permitted.

In the Plan's unfettered discretion and without notification to any respondent, the Plan may post any responses obtained by the Plan under this RFI, and items derived therefrom, on the Plan's public website (www.shpnc.org). In posting such items to the Plan's website, the Plan will post the redacted version of such items, if respondent has provided redactions in compliance with this section. If no redacted version of such items has been provided to the Plan in compliance with this section, the Plan will post such items on the Plan's website in the manner they were provided to the Plan.

Redacted copies provided by respondents to the Plan may be released in response to SPRA requests without notification to the respondent. Further, respondent's information that cannot be shown to be prohibited from disclosure by the SPRA may be subject to public disclosure under the terms of the SPRA.

If a legal action is brought to compel the Plan to disclose any of the respondent's redacted information, the Plan will notify the respondent of such action and consent to intervention of the respondent in the action and to the respondent's defense of the confidential status of the redacted information. In such legal action, the duty and responsibility to defend such information shall solely be the respondent's, and the Plan shall have no liability to the respondent for the Plan's failure to defend such action.

E. Respondent Materials

All responses, inquiries, or correspondence relating to or referenced in this RFI, and all documentation submitted by the various respondents shall become the property of the Plan when received. Ideas, approaches, information, recommendations, potential solutions, and options (but not proprietary material) presented by respondents may be used in whole or in part by the Plan in developing a future solicitation, should the Plan decide to proceed with a solicitation. Further, combinations of various responses from respondents may also become part of a solicitation, based on the needs of the Plan.

Response to the State of North Carolina (RFI No. 270-20240419GLP)

Respondent Name:
AmVentureX, Inc. (d/b/a Biocoach)
225 S 6th Street, STE 2560, Minneapolis, MN 55402
1-800-587-5496
www.BiocoachHealth.com

Main Contact Information:
Name: Matt Payne
Title: CEO
Email: matt@biocoach.io
Direct: (507) 269-0155

Name: Michael Silverstein
Title: CPO
Email: michael@biocoach.io
Direct: (507) 269-0155

May 29, 2024
Michael Silverstein, Chief Product Officer

Table of Contents

I. Overview

Introduction:

The purpose of this response is to address the Request for Information (RFI) issued by the State Health Plan of North Carolina. The RFI seeks comprehensive and financially sustainable solutions for covering GLP-1 and GIP-GLP-1 agonists for weight loss. The State Health Plan is focused on managing the rising costs associated with these medications while ensuring that members who need them have access. The Plan requires solutions that are effective in improving health outcomes and financially sustainable over the long term, aiming to reduce the financial burden, improve member health, and ensure long-term viability through ongoing monitoring and evaluation.

Biocoach proposes serving as the **Obesity Center of Excellence (CoE)** that allows the State Health Plan of North Carolina to cover Anti-Obesity Medications (AOMs). CoEs are well-established in U.S. healthcare, improving value in various conditions such as cancer and knee replacements. Typically, CoEs for acute conditions involve providers taking on outcome-based risks. Chronic condition CoEs, like those for diabetes, usually operate on a fee-for-service (FFS) model, allowing for continuous long-term management.

Key Features of an Obesity CoE:

An obesity Center of Excellence (CoE) diverges from traditional healthcare models in several compelling ways. Because obesity is a chronic condition, it demands long-term management and sustained support. Telehealth becomes a key component to supplement in-person care, as outcomes are easily measurable, allowing for remote and frequent monitoring through a high-touch model. Essential coordination with other healthcare providers is necessary due to the common presence of comorbid conditions.

1. **Comprehensive Care**: provides holistic care integrating obesity treatment protocols, developing personalized plans for short-term and long-term weight management, aligning incentives for all stakeholders.

   How Biocoach Will Support This: Biocoach assigns each member with a personal certified lifestyle coach who can support the member seeking treatment for obesity. They work to develop a personal relationship and understand the members goals and objectives. Once the coach meets with the member, they can refer them to a credentialed obesity specialist in your network. The coach will follow up and stay engaged with the member throughout their treatment – coordinating with the key stakeholders. Driven by the coaching, emotional support and socialized health become a driving force in the members' overall success in the program.

2. **Lifestyle Support**: offers dietary, exercise, and emotional support to help patients sustain healthy changes, including financial counseling and integration with existing employer wellness programs.

   How Biocoach Will Support This: The coach will be able to provide high-touch engagement with the member to support them making the necessary lifestyle changes. This is delivered via a HIPAA complaint mobile platform with many helpful features to support lifestyle change like meal planning, data tracking, masterclasses and more. Furthermore, based on the members' needs, the coach can activate a Biocoach care team member to engage with the member for additional support. This may include a patient navigator to help get them to resources that will help along their journey.

3. **Pharmaceutical and Procedural Interventions**: Prescribes anti-obesity medications based on patient needs, enhancing treatment effectiveness and adherence.

   How Biocoach Will Support This: To align incentives with both the member and the plan, Biocoach does not prescribe the anti-obesity medications. Instead, Biocoach contracts with credentialed and qualified obesity specialists in its network. This ensures that members are getting prescriptions from reputable obesity specialists, discourages over-prescribing, and ensures the patient will receive quality care.

4. **Integration with Primary Care**: Ensures continuity and coordination of care with patients' primary and specialty providers, facilitating efficient and personalized treatment plans.

   How Biocoach Will Support This: The members coach will create a pipeline of communication with the Primary Care Provider, ensuring that the Primary Care Provider is aware of the members care plan and progress.

In Summary:

In order for the State Health Plan to be able properly assess the feasibility of providing benefit coverage to Plan members to use GLP-1, GIP-GLP-1 agonists for weight loss, a full actuarial assessment and ROI estimate based on the Plans data must be created.

With our partner *Milliman* - a global leader in actuarial assessments - we are proposing a phased approach that will give the Plan the ability to model impacts to plan design, and implement coverage in a manner that is financially sustainable for the Plan. The phases are as follows:

Phase 1: Initial Landscape Assessment
Phase 2: Plan Design & Forecasting
Phase 3: Plan Implementation
Phase 4: Reporting & Monitoring

Key Benefits and Objectives Addressed:

- **Financial Sustainability:** The *initial landscape assessment*, careful *plan design and forecasting* aims to implement a fiscally responsible pricing framework that reduces the financial burden on the State Health Plan, aligning with the RFI's objective to explore financially sustainable solutions for covering GLP-1 medications. This effort will be led by our globally recognized actuarial partner *Milliman*. *Milliman* has reviewed this RFI and will partner to build modeling scenarios.
- **Long-Term Viability:** Ongoing *reporting and monitoring* will ensure that our solution is continuously evaluated for long-term success, focusing on sustainable outcomes and reducing overall healthcare costs through improved management of obesity, which meets the RFI's requirement for an effective and sustainable coverage model.

Financial Projections:

Estimated Net Cost for GLP-1 Coverage for Obesity in 2025

With unmitigated GLP-1 Coverage	**With Biocoach**
$170,000,000*	**$43-92,000,000**

*Estimations based on Publicly Available Information and data from SHP Board of Trustees Meeting January 25, 2024.

The above financial projection is based on a proprietary program developed by Biocoach. that needs to be fine tuned in Phases 1 and 2 below. We expect to achieve significant cost savings (45% - 75% projected savings) for the State Health Plan using our combined approach, leading to improved short term and long term health outcomes for members while decreasing overall drug spend on GLP-1.

The final model will take into consideration the following scenarios:

1. **State of North Carolina Project Budget and Goals:**
    - If provided the opportunity to develop a deeper integration with the State Health Plan, we take deep consideration into the State's budgetary goals and expectations to allow for GLP-1 coverage plan sustainability and feasibility. Our Phase 1 and 2 programming is designed to take great care to include guardrails and stricter eligibility requirements as needed, to control the budget forecasts. The actuarial assessments will provide the minimal recommended solutions for desired outcomes during this process.

2. **Approved Weight Loss Programs or Nutrition Classes:**
    - The actuarial assessment will evaluate the cost-effectiveness and outcomes of requiring members to complete approved weight loss programs or nutrition classes before medication approval. *Milliman* will help determine the financial impact and potential savings of implementing such prerequisites.
3. **Developing Step Therapies:**
    - *Milliman* will analyze data to identify effective step therapies involving lower-cost medications. This assessment will provide insights into cost savings and the potential reduction in overall medication expenses by establishing a step therapy protocol.
4. **Expert Prescription Requirements:**
    - The actuarial assessment will examine the benefits and costs associated with requiring medications to be prescribed by practitioners with appropriate expertise. This analysis will ensure that only qualified practitioners prescribe GLP-1 and GIP-GLP-1 agonists, improving treatment quality and member outcomes.
5. **Prohibiting Telehealth BMI Measurements:**
    - Our approach will assess the impact of prohibiting telehealth BMI measurements on program costs and accuracy. The assessment will explore alternative data collection processes that maintain accuracy and accountability while supporting successful benefit implementation.
6. **BMI and Current Weight:**
    - The actuarial assessment will evaluate the inclusion of BMI and current weight as criteria for medication eligibility. Milliman will analyze how these parameters affect program costs and member outcomes, ensuring that the Plan targets members who would benefit the most.
7. **Documented History of Lifestyle Modifications:**
    - Our approach will review the effectiveness and cost implications of requiring documented lifestyle modifications, such as reduced calorie intake and increased physical activity, before approving medication coverage.
8. **Enrollment in Nutritional or Dietary Programs:**
    - The actuarial assessment will analyze the impact of documented enrollment and measurable participation in other nutritional or dietary programs. This will include evaluating how these programs influence medication efficacy and overall program success.
9. **Consideration of Comorbid Conditions:**
    - The actuarial assessment will assess the role of comorbid conditions and other obesity-related medical conditions in determining eligibility for GLP-1 and GIP-GLP-1 agonists. This analysis will help tailor the program to address the needs of members with complex health profiles.
10. **Data Analytics and Reporting Tools:**
    - The actuarial assessment will identify and recommend data analytics and reporting tools that support successful claims adjudication and program evaluation. We will ensure that these tools provide actionable insights for ongoing program improvement.

11. **In-Person Treatment Visits:**
    - Our approach will evaluate the necessity and impact of requiring in-person treatment visits to verify the efficacy of medications. This assessment will balance the need for accurate efficacy verification with program costs and member convenience.
12. **Additional Considerations and Parameters:**
    - Our approach will explore and recommend any additional considerations or parameters that would support the Plan's objectives. This could include innovative approaches to utilization management and targeted interventions to maximize program effectiveness and member health outcomes.

To implement these variables, Biocoach suggests implementing a CoE model.

Biocoach proposes serving as the **Obesity Center of Excellence (CoE)** for the State Health Plan of North Carolina to cover Anti-Obesity Medications (AOMs) for members who need it most, while ensuring costs remain sustainable. The CoE model outlined in the white paper in Addendum A of this proposal outlines the functions and benefits of a CoE in detail. These include:

1. **Aligned Incentives**: Only patients who will truly require it will receive high-cost therapies like GLP-1 drugs.
2. **Member Support**: Enhanced support, through deeply personalized health coaching and advocacy, ensures patients adhere to their therapy and lifestyle changes, driving improvements in both short term and long term outcomes for members seeking or taking GLP-1 medications. ‘
3. **Formulary Stability**: The plan can choose to maintain their formularies without restricting access, *keeping drug rebates unaffected.*
4. **Cost Reduction & Predictability**: The plan can avoid exponential cost increases and may achieve significant cost reduction with a specialty capitation CoE financial model.

II. Process & Integration

Biocoach will operationalize the Obesity CoE in four main phases. This approach allows the State Health Plan control over both the financial and clinical implications of AOM coverage in a systematic way. It also provides a clear financial model and roadmap for coverage that can be adjusted as needed.

Phase 1: Conduct a Landscape Assessment:

Conducted in partnership with *Milliman*, this assessment will analyze the current state of obesity treatment coverage, utilization patterns, and financial impacts. The goal is to identify opportunities for cost savings and improved outcomes.

Goal: Determine the range of options available for covering GLP-1 drugs and cost estimates for each.

Description: Analysis of the current market scenario surrounding GLP-1 drugs which are known for their high costs. This assessment will provide a comprehensive background on the escalating prices of GLP-1 drugs, shedding light on the factors contributing to this trend. It will explore the potential consequences if these rising costs remain unchecked, including the financial burden, the accessibility of these medications for patients, and the overall impact on public health.

This study aims to present a clear picture of the current utilization and cost, insurance coverage, and market dynamics of these drugs. It will also offer valuable insights into potential coverage strategies and interventions that could be employed to control these escalating costs.

Required data: 12 months of claims and membership data for the State Health Plan of North Carolina (alternatively, data can be sourced from the T-MSIS data within CMS's VRDC environment, however this would incur a research charge in addition to the costs estimated below)

Process:

1. Ingest claims and membership data
2. Clean data fields and process through the Milliman HCG Grouper
3. Summarize GLP-1 utilization and cost trends and forecast two years into the future
4. Simulate GLP-1 utilization and cost trends and forecasts based on the landscape of GLP-1 coverage options

Deliverables:

- Detailed report and spreadsheet-based exhibits calculating the value of different approaches to covering GLP-1 drugs for review.

Phase 2: Plan Design & Forecasting:

Part 1: Plan Design ROI Assessment

Goal: Design a Plan - Determine the value of different options for the State Health Plan of North Carolina. Based on the findings from the landscape assessment, Biocoach in partnership with *Milliman,* will create a customized ROI calculator to determine the value of different options for the Plan.

Description: A detailed ROI calculator used to demonstrate total financial value of the GLP-1 models of care, in order to guide program design and decision making. This calculator will incorporate health plan data, prevalence of targeted population types, demographic and geographic differentiation, and cost data for specific diagnoses.

The structure of the model could be developed in collaboration with the State Health Plan of North Carolina to account for the measurable components of the preferred model of care and potential interventions designed for better healthcare outcomes. Such a model would likely include baseline and care model assumptions, as well as assumptions on the types of services used by the population.

The goal of the calculator is to cover the demonstrable value of intervention options, including improvements in medication adherence, behavior change, and population health measures. Note that this is subject to the limitations of time and budget, if getting all the details of the value and program leads to unanticipated scope. We can give guidance on what estimation and modeling techniques could meet the need and still stay within budget.

Required data: None (assuming the landscape assessment is complete)

Process:
1. Synthesize the entire demonstrable value of the interventions
2. Prepare assumptions and baseline cost and utilization data
3. Create ROI model framework and calculations
4. Integrate assumptions and baseline data into the model framework
5. Review calculations and scenario test model

Deliverables: Excel-based ROI calculator

Part 2: Plan Design Development

Goal: In collaboration with the State Health Plan and based on data from the ROI calculator and landscape assessment, design a comprehensive plan and financially

sustainable solutions for covering GLP-1 and GIP-GLP-1 agonists for weight loss.

Description: Based on the assessment and ROI modeling data, Biocoach will work to implement and operationalize the Obesity CoE. This will include any recommendations for patient eligibility, utilization management strategies, cost-sharing requirements, provider credentialing, provider contracting, establishing quality and operational metrics, member attribution, performance period tracking and monitoring, and any other financial considerations.

The key elements of this plan will focus on key levers:

- Number of members clinically qualified for AOM coverage
    - Patient eligibility is a key factor in determining this. For example currently 48-55% of the commercial age population is eligible based on FDA labeling instructions. Modifying patient eligibility will have a rebate impact, but the net cost to the plan could be significantly less even with rebate impact depending on the qualification standards.
- Average Annual Net Cost For GLP-1
- Number of members qualified that start therapy
    - Utilization Management: Prior Authorization, Step Therapy and other utilization management strategies can impact the number of enrollees who start therapy. It is very likely that rebates will be impacted, however the net cost of the drugs to the plan may still be less if a system is in place.
    - Cost-sharing: Increasing the copay for these medications is known as a “silent” prior authorization. However this method can increase health disparities as only people who can afford the copay will be able to utilize the medication.
- Number of members who drop off
    - As data suggests, 68% of people who start taking GLP-1 medications drop off before year 1. This leads to medication waste. Focusing on supporting members who are taking it to achieve clinically significant weight loss is a key consideration when determining net cost and ROI.

Biocoach will serve as an administrative hub to coordinate and facilitate stakeholders including the State Health Plan, *Milliman*, CVS/Caremark, specialty clinics and other third-party vendors.

As an independent third-party, Biocoach solely works for the plan, its incentives are aligned to find the best coverage solution and plan design. PBMs, specialty clinics, and other third-parties often have competing incentives that are counter to the goals of the Plan.

The goal of this will be to have a clear roadmap to implementation with measurable financial and clinical components in-place.

Process:

1. Determine a coverage strategy based on the ROI assessment.
2. Work with PBM and develop systems and processes to implement coverage strategy – taking into consideration patient eligibility requirements, utilization management strategies, and cost-sharing requirements.
3. Establish quality and operational metrics based on the process.
4. Contract with specialty clinics capable and qualified to support the strategy.
5. Create a care pathway and simple onboarding process for members to navigate.

Deliverables:

A written coverage plan that includes:

- Patient eligibility requirements
- Utilization management & cost sharing requirements
- Tracked Metrics type and frequency
- Workflow of member experience
- Specialty clinical credentialing requirements

Phase 3: Plan Implementation

Goal: Successfully rolling out the Obesity CoE, ensuring seamless integration with existing infrastructure and effective communication to drive member engagement and program uptake.

Description: This phase focuses on launching the designed plan, promoting the program to members, and ensuring all systems are operational. It involves marketing efforts, member onboarding, training for support staff, and establishing monitoring processes to track the implementation's success.

Process:

1. Marketing and Communication:
    - Develop a comprehensive marketing strategy to promote the Obesity Center of Excellence (CoE) to eligible members.
    - Utilize various communication channels (e.g., email, social media, webinars, mailers) to inform members about the program benefits and how to enroll.
    - Collaborate with the State Health Plan to include information about the CoE in their member communications.
2. Member Onboarding:
    - Implement a streamlined onboarding process that guides new members through the steps of joining the CoE and accessing support.
    - Provide clear instructions and support materials (e.g., FAQs, tutorials, helpline) to assist members with registration and initial setup.
    - Host informational webinars and Q&A sessions to address member concerns and provide detailed program information.
3. Training and Support:

- Conduct training sessions for personal health coaches, patient navigators, and dietitians to ensure they are fully prepared to support members.
- Equip support staff with the necessary tools and resources to effectively engage with members and track their progress.
- Establish a dedicated support team to handle member inquiries and provide ongoing assistance.

4. System Integration and Deployment:
    - Ensure the technology platform (mobile app and admin dashboard) is fully operational and integrated with existing health plan systems.
    - Verify that data tracking and reporting functionalities are working correctly to capture relevant health metrics and member engagement data.
    - Coordinate with the Pharmacy Benefit Manager (PBM) to integrate prescription management systems.
5. Monitoring and Evaluation:
    - Implement monitoring processes to track key performance indicators (KPIs) and program outcomes.
    - Regularly review data to assess the program's effectiveness and identify areas for improvement.
    - Provide feedback to stakeholders and adjust the implementation strategy as needed to ensure optimal performance.

Deliverables:

- Marketing Materials: Campaign plans, promotional content, and communication templates.
- Member Onboarding Kit: Welcome packets, instructional guides, and webinar schedules.
- Monitoring Reports: Regular performance and outcome reports, including member engagement metrics and program impact analyses.

Phase 4: Reporting & Monitoring

Goal: Ensure the ongoing success of the obesity management plan through continuous data analysis, outcome tracking, and financial performance reviews. Make necessary adjustments to maintain long-term viability and effectiveness.

Description: This phase involves establishing robust reporting and monitoring processes to track the effectiveness of the implemented plan. Regular analysis of health outcomes, member engagement, and financial performance will be conducted to ensure the program meets its goals and delivers value to the State Health Plan and its members.

Process:

1. Data Collection and Integration:
    - Collect comprehensive data on member engagement, health outcomes, and financial metrics from various sources, including the mobile app, wearable devices, PBM, and healthcare providers.

- Ensure all data is integrated into a centralized system for streamlined analysis and reporting.

2. Performance Tracking:
    - Track key performance indicators (KPIs) such as medication adherence rates, weight loss percentages, engagement levels, and health improvements.
    - Monitor financial metrics, including cost savings, return on investment (ROI), and budget adherence.
3. Regular Reporting:
    - Generate monthly, quarterly, and annual reports to provide insights into program performance.
    - Develop customized dashboards for stakeholders to access real-time data and performance metrics.
    - Share detailed reports with the State Health Plan, highlighting progress, achievements, and areas for improvement.
4. Outcome Analysis:
    - Conduct in-depth analysis of health outcomes to assess the effectiveness of the obesity management plan.
    - Compare actual outcomes with projected goals to identify discrepancies and areas needing attention.
5. Financial Performance Reviews:
    - Review financial performance regularly to ensure the plan remains cost-effective and financially sustainable.
    - Analyze cost trends, utilization rates, and savings achieved through the program.
    - Adjust financial strategies as needed based on the reviews to maintain budget alignment and optimize cost management.
6. Feedback and Adjustments:
    - Gather feedback from members, coaches, and healthcare providers to identify potential improvements.
    - Implement necessary adjustments to the program based on data analysis and stakeholder feedback.
    - Continuously refine and enhance the program to ensure it meets evolving needs and achieves long-term success.
7. Compliance and Quality Assurance:
    - Audit claims, rebates, and prior authorizations for accuracy
    - Ensure compliance with relevant regulations and standards.
    - Conduct regular quality assurance checks to maintain high standards of care and service delivery.
    - Address any compliance issues promptly and adjust processes to prevent future occurrences.

Deliverables:

- Monthly, Quarterly, and Annual Reports: Comprehensive reports on member engagement, health outcomes, and financial performance.

- Customized Dashboards: Real-time access to key performance metrics and data insights for stakeholders.
- Outcome Analysis Reports: Detailed analysis of health outcomes and program effectiveness.
- Financial Review Reports: Regular reviews of financial performance and cost management.
- Feedback Summaries: Reports summarizing feedback from members, coaches, and providers, along with proposed adjustments.
- Quality Assurance Reports: Regular checks and compliance reports ensuring high standards of care.
- Annual Claims Audit Report

III. Eligibility Parameters & Utilization Management

Biocoach along with *Milliman's* actuarial assessment will help the plan achieve the following objectives. Here is how our approach will help the Plan achieve its objectives.

Establishing Eligibility Requirements for Benefit Coverage:

1. **Approved Weight Loss Programs or Nutrition Classes:**
    a. The actuarial assessment will evaluate the cost-effectiveness and outcomes of requiring members to complete approved weight loss programs or nutrition classes before medication approval. *Milliman* will help determine the financial impact and potential savings of implementing such prerequisites.
2. **Developing Step Therapies:**
    a. *Milliman* will analyze data to identify effective step therapies involving lower-cost medications. This assessment will provide insights into cost savings and the potential reduction in overall medication expenses by establishing a step therapy protocol.
3. **Expert Prescription Requirements:**
    a. The actuarial assessment will examine the benefits and costs associated with requiring medications to be prescribed by practitioners with appropriate expertise. This analysis will ensure that only qualified practitioners prescribe GLP-1 and GIP-GLP-1 agonists, improving treatment quality and member outcomes.
4. **Prohibiting Telehealth BMI Measurements:**
    a. Our approach will assess the impact of prohibiting telehealth BMI measurements on program costs and accuracy. The assessment will explore alternative data collection processes that maintain accuracy and accountability while supporting successful benefit implementation.

Establishing Utilization Management Parameters:

1. **BMI and Current Weight:**
    ○ The actuarial assessment will evaluate the inclusion of BMI and current weight as criteria for medication eligibility. *Milliman* will analyze how these parameters affect program costs and member outcomes, ensuring that the Plan targets members who would benefit the most.
2. **Documented History of Lifestyle Modifications:**
    ○ Our approach will review the effectiveness and cost implications of requiring documented lifestyle modifications, such as reduced calorie intake and increased physical activity, before approving medication coverage.
3. **Enrollment in Nutritional or Dietary Programs:**
    ○ The actuarial assessment will analyze the impact of documented enrollment and measurable participation in other nutritional or dietary programs. This will include evaluating how these programs influence medication efficacy and overall program success.
4. **Consideration of Comorbid Conditions:**

    - The actuarial assessment will assess the role of comorbid conditions and other obesity-related medical conditions in determining eligibility for GLP-1 and GIP-GLP-1 agonists. This analysis will help tailor the program to address the needs of members with complex health profiles.
5. **Data Analytics and Reporting Tools:**
    - The actuarial assessment will identify and recommend data analytics and reporting tools that support successful claims adjudication and program evaluation. We will ensure that these tools provide actionable insights for ongoing program improvement.
6. **In-Person Treatment Visits:**
    - Our approach will evaluate the necessity and impact of requiring in-person treatment visits to verify the efficacy of medications. This assessment will balance the need for accurate efficacy verification with program costs and member convenience.
7. **Additional Considerations and Parameters:**
    - Our approach will explore and recommend any additional considerations or parameters that would support the Plan's objectives. This could include innovative approaches to utilization management and targeted interventions to maximize program effectiveness and member health outcomes.

Examples of parameters used:

- Number of members clinically qualified for AOM coverage
    - Patient eligibility is a key factor in determining this. For example currently 48-55% of the commercial age population is eligible based on FDA labeling instructions. Modifying patient eligibility will have a rebate impact, but the net cost to the plan could be significantly less even with rebate impact depending on the qualification standards. Options include:
        - No changes to FDA labeling eligibility criteria
        - Requiring 30 BMI
        - Requiring 30 BMI + 1 comorbidity
        - Requiring 35 BMI
        - Requiring 35 BMI + 1 comorbidity.

- Number of members qualified that start therapy
    - Utilization Management: Prior Authorization, Step Therapy and other utilization management strategies can impact the number of enrollees who start therapy. It is very likely that rebates will be impacted, however the net cost of the drugs to the plan may still be less if a system is in place. Options will range from:
        - No requirements or utilization options.
        - Require 3-6 months of lifestyle change with Biocoach
        - Require 3-6 months of an oral medication with Biocoach program
        - Require enrollee to join Biocoach program while on therapy
        - Incentivise with lower co-pay if they join Biocoach
        - Require higher copay for medications.

Specific eligibility parameters and utilization management strategies will be determined based on the landscape assessment and ROI modeling. These parameters will be based on a multivariate analysis taking into account rebate impacts etc.

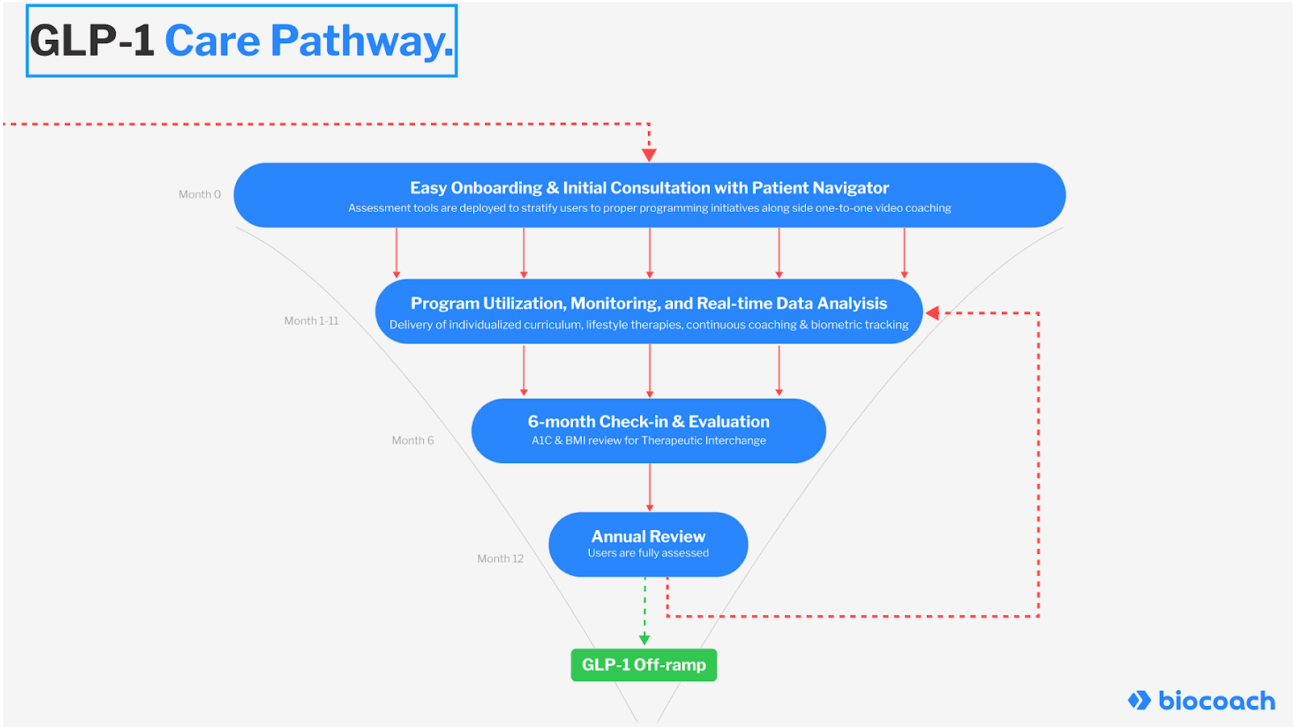
The results of these models will establish clinical criteria necessary for an individual to be eligible for care through the CoE, including factors such as BMI, body fat percentage, and the presence of comorbidities.

Treatment guidelines, such as those from ACE/AACE, can be used to define the eligibility criteria for the CoE population. The CoE should categorize members based on the severity of their obesity and any comorbidities, and also plan for the long-term support needed for ongoing weight maintenance.

There is a possibility of not modifying eligibility parameters given a sustainable model – but that will need to be determined in Phases 1 and 2.

IV. Care Pathways & Clinical Considerations

Depending on the individual cases, Biocoach offers care pathways that include patient evaluation, step therapies and 6-month on-ramp, GLP-1 case management while on the medication, and then a 6-month off-ramp to support maintenance and prevent rebound weight gain. All of these pathways include constant analysis, oversight, and performance reporting.



Clinical Considerations:
A program that is based on simply eating less and moving more is not sufficient to support members taking GLP-1. A metabolic approach to these medication is more appropriate which focuses on:

- Optimizing Macronutrient Intake: Studies show that 39% of the weight lost is lean muscle mass. Muscle is our most metabolically active organ which regulates calorie burning and glucose uptake. Many people who take GLP-1 are not taught to consider this and therefore don't get enough protein in their diet.
- Optimizing Micronutrient Intake: Because GLP-1s increase satiety, it is important that when you do eat you are considering nutrient dense whole foods. Biocoach makes this easy with our meal planning and grocery list feature.
- Side effect mitigation: Certain foods can exacerbate common side effects. It's important to know which foods those are.

- Managing hormone fluctuations: These drugs can significantly alter hormones which regulate hunger. Ensuring that you are eating foods which mitigate these effects can help people while they're on the medication and when they come off.

Coaching + Food Delivery Drives Significant Savings:
A study conducted by North Carolina Blue Cross Blue Shield found that completion of a coaching and food delivery program was associated with a reduction of $139 per member per month (PMPM) in total medical costs.

Shrank, W., Saunders, R., McClellan, M., & Milstein, A. (2022). Meeting the Demand for Health Care: Transforming the Workforce for a Value-Based System. NEJM Catalyst Innovations in Care Delivery, 3(4). https://doi.org/10.1056/CAT.22.0351.

As a part of the Biocoach program, people receive a monthly stipend for groceries powered by our partnership with Instacart.

Members will be able to receive a custom meal and grocery list built for their GLP-1 program, and be able to have that plan delivered by Instacart all in our technology platform. This ensures members are receiving proper nutritional intake at all phases of GLP-1 usage, while teaching members long-term strategies for maintaining the weight loss through lifestyle design and dietary choices.

V. Cost and Expense Information:

Below is the initial pricing for Biocoach programming.

Item	Description	Estimated Pricing*
CoE Admin Fee	Covers Phases 1-2-3-4	$0.85 PMPM
Utilization Fee	Biocoach CoE + GLP-1 Personal Coaching	$59 - $149 Per *Utilized* Member Per Month + Value-Based Rebates/Options

**Additional pricing and cost options can be broken out upon request. This cost reflects an estimated total cost of ownership for the solution including continued compliance with emerging industry standards.*

VI. Respondent's Experience and Qualifications:

Biocoach was recently awarded a five-year $12.5 Million dollar cooperative agreement with the CDC to serve as an administrative hub to scale the **National Diabetes Prevention Program**. We are working with multi-sectoral partners across the country to increase enrollment - especially for priority populations.

This work requires significant coordination and effort across payers, health systems, community based organizations, and delivery partners. The model is similar to our Obesity Center of Excellence in that we will be serving as a hub for the system.

We have worked with payers facing similar challenges to the State Health Plan, and are able to tap into our vast network of experts and partners to support the goals of this RFI.

Overview of Biocoach:
Biocoach is dedicated to transforming health outcomes through innovative, personalized health coaching and care navigation. Our mission is to give people the power to engage in their health by delivering deeply personalized support during obesity care.

Through our care team, we focus on building meaningful relationships that support members in improving their health. The Biocoach program offers the following components for health plans and their members:

For Health Plans:
- The Biocoach Obesity Center of Excellence (CoE)
- GLP-1 Plan Design & Forecasting
- Solution Integration & Case Management
- Data Tracking and Performance Reporting

For Members:
- Coaching & Care Team
    - All members will gain access to a personal health coach and care team. GLP-1 program members are provided with deeper support with our high-touch approach.
    - Available via video and mobile phone.
    - Board Certified health coaches with a variety of experiences (Diabetes, sports medicine, emotional support, etc).
    - Patient navigators and advocates who can help connect members to specialty care and directly communicate with their doctor.
- Diabetes & Pre-diabetes Care w/ our DEFENDER Program
    - Personalized classes and programs including:
        - An obesity program for weight loss and overall metabolic health
        - A CDC-recognized diabetes prevention program delivered to all of your qualified members
- Nutrition Planning
    - Dietitian and health coach guidance provided to all members

    - A weekly meal planning assistant which builds a custom meal plan and grocery list based on members recent biometric health data and goals.
    - The meal plans are highly personalized to fit practically into each members' lifestyle. This includes meal plans that are custom designed for the whole family, their weekly grocery budgets, ingredient preferences, and even home cooking equipment.
    - GLP-1 Targeted Programming - Our care team pays extra attention to members on GLP-1 medication, ensuring proper nutrition is delivered, to reduce side effects and lean muscle loss during weight loss.
    - Optional: Integration with Instacart where members receive a monthly stipend for Fresh Groceries delivered to their doorstep to improve access to fresh foods, even in rural locations, while incentivising the members to engage in the meal planning.
- Innovative Mobile App
- Biometric Tracking and Monitoring
    - Integration with wearable and phone data from Apple Health & Google Fit (steps, weight, calories, exercise, sleep, heart rate, and more)
    - Biomarker tracking (e.g. A1C, glucose)
    - We offer direct-shipped smart glucose monitors and at-home A1C Testing Kits

Milliman is a global leader in healthcare actuarial science, and has written extensively on GLP-1 coverage, cost implications, and strategies.

Founded in 1947, *Milliman* is an independent risk management, benefits, and technology firm with a global presence. *Milliman* serves a diverse range of clients, including businesses, financial institutions, governments, unions, educational institutions, and nonprofits.

Milliman's multidisciplinary team includes actuaries, technologists, clinicians, economists, climate and data scientists, and benefits and compensation experts.

Milliman's actuarial services are known for their precision and reliability. The firm's expertise in healthcare, particularly in financial modeling and risk assessments, makes it a trusted partner for managing costs and improving health outcomes. *Milliman* uses data analytics and advanced modeling techniques to provide actionable insights and strategic guidance.

VII. Technical Requirements

Biocoach operates using a highly accessible and efficient technological framework that requires minimal infrastructure investment. Our solution is centered around a mobile app and a web/cloud-based system designed to provide seamless access and user experience.

- For members: Mobile Application Requirements:
    - The Biocoach mobile app is available for both iOS and Android devices. Users only need an iPhone or an Android smartphone to access the full suite of Biocoach services, including live coaching, data tracking, virtual classes, and personalized meal plans.
- For Health Plan: Web-Based System Requirements:
    - Our admin dashboard and other web-based tools are fully cloud-based, ensuring secure and reliable access from any location. The system requires only a modern web browser (e.g., Google Chrome, Mozilla Firefox, Safari, or Microsoft Edge) to operate. There is no need for specialized hardware or software installations.

By leveraging our robust framework, Biocoach ensures that the state health plan can deploy and manage our solution with ease, minimizing the need for additional IT infrastructure or extensive training.

Data Storage, Security, and Compliance:

Our architecture and data infrastructure is designed to be fully HIPAA compliant, ensuring that all patient data is encrypted, both in transit and at rest, with access strictly controlled and monitored. We maintain rigorous auditing processes and employ a secure database environment that meets or exceeds all HIPAA requirements to safeguard personal health information. Some key features of our compliance and security architecture include, but are not limited to:

Access Management:

- Multi-factor Authentication: Ensures secure access with layers of authentication and seamless integration with enterprise single sign-on systems.
- Centralized Identity and Access Management: Manages permissions through role-based access controls, enhancing security by ensuring only authorized users access sensitive data.
- Activity Monitoring: Logs and monitors all platform activity, providing transparency and enabling quick response to any unusual actions.

Auditing and Monitoring:

- Comprehensive Logging: Includes detailed logging of container activities, SSH sessions, and real-time access, ensuring all actions are traceable.
- Intrusion Detection: Monitors for unauthorized access and potential security breaches both at the host and network levels, with 24/7 incident response.

Data Protection and Privacy:

- Encryption: Implements robust encryption protocols for data at rest and in transit, using strong ciphers and forced HTTPS to protect data integrity and confidentiality.
- Endpoint and Network Security: Employs advanced filtering and security configurations to protect against unauthorized access and ensure data is only accessible to permitted networks and IPs.

High Availability and Server Reliability:

- Redundant Infrastructure: Ensures high availability through multi-region deployments and automatic recovery systems to maintain service continuity.
- Backup and Disaster Recovery: Automatic and frequent backups, tested regularly for reliability, ensure data preservation and swift recovery in any event.

VIII. Conclusion

We appreciate the opportunity to present our proposal for the Biocoach solution to support the State Health Plan. Our comprehensive care management program is designed to address the growing needs and high costs associated with obesity and related chronic conditions, providing a targeted, data-driven approach to improve health outcomes and reduce overall healthcare expenses.

Key Benefits:

- Data-Driven Solutions: Starting with the detailed landscape analysis, will allow us all to make informed decisions around plan design and budgeting. Then member tracking and permanence reporting ensures our systems are functioning properly throughout the scope of the project.
- Comprehensive Care Management: Supporting patients through their treatment journey.
- Tailored Plan Design: Customizing plans to fit specific goals and financial capabilities.
- Support for Whole Population: Including lifestyle therapy, diabetes prevention, and meal planning for all employees.
- ROI and Cost Management: Aiming for a positive ROI and potential cost savings.

Our solution leverages state-of-the-art technology, requires minimal infrastructure, and integrates seamlessly with existing systems, ensuring a smooth implementation process. The Biocoach program is poised to deliver significant health improvements and financial savings, making it an ideal partner for the State Health Plan.

Next Steps:

We are available for any follow-up meetings or discussions to clarify any aspects of our proposal. Should you require further information or wish to schedule a demonstration of our system, please do not hesitate to contact us.

Contact Information:

Matthew Payne, CEO
Phone: (510) 750-9028
Email: matt@biocoach.io

We look forward to the possibility of partnering with the State Health Plan to enhance the well-being of your members through our innovative and effective care management solutions. Thank you for your consideration.

IX. Appendix

Addendum A: *Employers and targeted obesity care: Exploring the concept of an obesity center of excellence*

Addendum B: *Payer strategies for GLP-1 medications for weight loss*

Employers and targeted obesity care: Exploring the concept of an obesity center of excellence

Assessing benefits, financial structures, and operational considerations

Jessica Naber, FSA, MAAA
Austin Barrington, FSA, MAAA
Bryce Platt, PharmD, RPh

Commissioned by Eli Lilly and Company

Milliman

A targeted obesity care model combined with a risk-sharing financial component may align provider and employer incentives for treatment of obesity.

Introduction

Obesity has become a significant public health concern in the United States (U.S.), with its prevalence increasing dramatically over the past few decades. According to the Centers for Disease Control and Prevention (CDC), the rate of obesity among adults in the U.S. is 41.9% as of 2020, an increase from 30.5% in 2000.[1] The pathology of obesity is complex, involving a combination of genetic, behavioral, metabolic, and environmental factors.[2] Individuals with obesity have a higher rate of certain comorbidities, including type 2 diabetes (T2D), cardiovascular diseases, metabolic syndrome, chronic kidney disease, depression, and others.[3] The impact of obesity in the workplace has resulted in less overall productivity and increased absenteeism, relative to employees who do not have obesity.[4,5] Moreover, individuals with obesity have a greater risk of all-cause mortality and cardiovascular-related mortality.[6]

Studies have shown weight loss for individuals with obesity leads to decreased health risks and therapeutic benefits for comorbidities.[7,8,9] However, in the current landscape of obesity treatment and management, several challenges exist. Stigma and negative stereotypes regarding obesity can influence the judgment and behavior of providers toward affected patients, potentially affecting the quality of care provided.[10] This stigma can lead to patients with obesity experiencing stress, avoiding care, mistrusting doctors, and having poor adherence to treatments.[10] Additionally, treatment approaches for obesity often lack coordination among providers, with patients having inadequate short- and long-term support. From a group health insurance point of view, employers have inconsistent coverage of obesity-related treatments, such as bariatric procedures and glucagon-like peptide-1 (GLP-1) agonist medications. According to recent studies of large employers, it is estimated that 45% of employers currently provide coverage for bariatric surgery,[11] and an anticipated 43%[12] to 49%[13] of employers will provide coverage in 2024 for GLP-1 medications indicated for chronic weight management. Comparatively, 92% of large employers currently cover GLP-1s for T2D.[13] More than half of the employers surveyed were “very concerned” about the long-term cost implications of GLP-1s.[13]

Currently, there exist a variety of programs and businesses targeted at the treatment of obesity. Employer wellness programs are aimed at promoting healthy behaviors and frequently include weight management components, but studies reveal mixed reviews on the ability of wellness programs to significantly impact health and economic outcomes for patients and employers.[14] Alternately, obesity telehealth programs have emerged as a way of offering targeted and individualized obesity care for employees. These programs typically include a virtual care model, diet and activity planning, metric tracking, and health coaching. The most popular obesity telehealth platforms have monthly per-subscriber fees, but the cost of medical services (e.g., labs) and prescription drugs are often not included in the fees.[15,16,17]

Given the current challenges related to the treatment of obesity and management of related costs, this white paper explores financial and operational considerations for creating a best-in-class treatment center for obesity, in the form of a center of excellence (CoE). The CoE would incorporate financially at-risk components associated with obesity treatment and outcomes, with a goal of consistent and appropriate care, sustainable patient outcomes, and long-term reductions in overall healthcare costs. By exploring the dynamics of an obesity CoE, this white paper aims to provide a conceptual solution for employers that aligns incentives among stakeholders in the treatment and management of obesity.

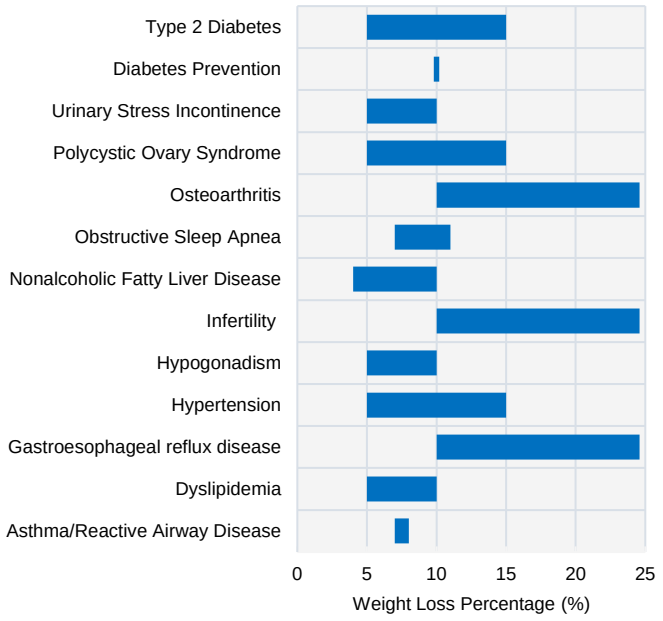
Note that the framework discussed herein is oriented toward an obesity CoE model for self-insured employers and their

employees; however, the model may be applicable to other types of payers and insurers as well.

Benefits of weight loss and obesity management

The American Association of Clinical Endocrinology (AACE) and the American College of Endocrinology (ACE) published obesity clinical practice guidelines in 2016. According to the guidelines, for most obesity-related conditions a loss of 5% to 10% of body weight can result in therapeutic benefits. Figure 1 summarizes the weight loss required for therapeutic benefits of 13 comorbidities related to obesity, as noted in the AACE/ACE guidelines.[18] Note that improvements due to weight loss for congestive heart failure and cardiovascular disease were ongoing or in the planning phase at the time of the AACE/ACE guidelines, and thus these diseases are not included in Figure 1.

FIGURE 1: WEIGHT LOSS (%) REQUIRED FOR THERAPEUTIC BENEFIT OF COMORBIDITIES (SUMMARIZED FROM AACE/ACE GUIDELINES[18])



Note: Additional therapeutic benefits may be seen at weight loss levels higher than what is displayed in this figure; the percentages in Figure 1 are supported by studies included in the AACE/ACE guidelines.

Therapeutic benefits of weight loss are numerous, including decreased blood pressure, decreased hemoglobin A1c levels, and improvements in inflammation, joint stress mechanics, and ovulation.[9] In one study, individuals with a body mass index (BMI) of 40 kg/m^2 who lost weight (median of 13% weight loss) had risk reductions for T2D of 41%, sleep apnea of 40%, hypertension of 22%, dyslipidemia of 19%, and asthma of 18%.[8]

The AACE/ACE guidelines recommend lifestyle modifications as a first line of treatment for obesity, which includes diet, physical activity, and behavioral modifications. Under certain circumstances, the guidelines also recommend medication-assisted weight loss in conjunction with lifestyle therapy, or bariatric procedures to help meet goals for clinical outcomes. Figure 2 summarizes recommended treatment guidelines across increasing BMI classes.

FIGURE 2: RECOMMENDEDED TREATMENTS BY BMI (SUMMARIZED FROM TREATMENT GUIDELINES[18,19])

CONSIDERATIONS FOR EMPLOYERS

From an employer's healthcare cost perspective, the financial implications of obesity can be significant. Adults ages 20 to 65 with obesity are estimated to incur annual medical expenses that are twice as high as those of adults with a normal weight. Additionally, average expenditures increase as BMI increases. Compared to a normal-weight cohort, annual medical expenditures are 1.7 times higher for class 1 obesity (BMI 30.0-34.9), 2.2 times higher for class 2 obesity (BMI 35.0-39.9), and 3.3 times higher for class 3 obesity (BMI ≥ 40.0).[20] Over 30 units of BMI, each one-unit BMI increase is associated with an additional cost of $253 per person per year (in 2019 dollars).[21]

Weight loss can lead to potential healthcare savings for employers. According to a publication that estimated weight-loss-associated decreases in medical care expenditures in a commercially insured population, individuals with obesity and chronic conditions can have estimated reductions in total medical expenditures ranging from $238 to $752 in annual savings for each one-point decrease in BMI unit.[22] Note that these savings estimates do not include the incremental cost of the care plan and/or treatment to achieve the BMI decreases.

In the workplace, weight loss can result in reduced job absenteeism, as individuals with obesity are estimated to miss three more days of work annually due to injury or illness compared to individuals with normal weight (5.3 days missed versus 2.3 days missed, respectively).[5] Presenteeism may also be improved with weight loss, given employees with a BMI ≥ 35 experience greater health-related work limitations—such as needing additional time to complete tasks and lower ability to perform physical job

demands—than the average worker.[23] More generally, employers who provide comprehensive healthcare coverage and offer wellness programs to their employees have been shown to increase employee job satisfaction levels and productivity, and decrease their likelihood of seeking other employment opportunities.[24,25]

Exploration of an obesity CoE model

A CoE is a dedicated facility or team within a healthcare organization that provides exceptional care and leadership in a specific area of medicine. It is characterized by a high concentration of specialized skills and resources, coupled with a commitment to research, education, and quality. A CoE typically aims to provide high-quality patient outcomes, advance medical knowledge, and reduce healthcare costs in its area of focus.

The concept of a CoE model is familiar to U.S. payers. CoEs have been implemented to improve value in multiple conditions and medical episodes from cancer to knee replacement.[26,27] The CoEs where providers are willing to take on risk for outcomes are typically targeted at conditions that are acute in nature or have a defined treatment period (e.g., oncology, kidney, musculoskeletal).[17,26,28] The CoEs that treat chronic conditions (e.g., diabetes or chronic obstructive pulmonary disease)[29,30] are often structured around a fee-for-service (FFS) payment model. Additionally, CoEs typically treat conditions prevalent in older populations, where Medicare may be able to benefit from longer-term clinical improvements due to the lower rate of member turnover or churn compared to commercial insurance. Lastly, CoEs typically have a physical facility where they see patients and may add telehealth services as additional support. For obesity treatment and management, a CoE provides best-in-class care through a specific provider network. An obesity CoE has a few key differences from typical CoE models in place today:

- Obesity is a chronic, long-term condition that requires ongoing support, even after weight-loss goals are achieved.
- A longer time horizon may be needed to realize cost savings associated with weight loss and other therapeutic benefits.
- Obesity and weight-related outcomes are generally easy to self-measure. Thus, an obesity CoE could provide treatment and support primarily through a telehealth platform, with referrals to in-person specialists, as needed.
- Individuals with obesity often have other conditions that are already being managed by a primary care provider or specialist. Thus, continuity of care and coordination among providers both within and outside of the CoE are essential.
- Obesity affects individuals of all ages, with the highest prevalence in older age groups.[1] However, Medicare is currently prohibited from covering weight-loss medications[31] and only covers bariatric surgery in certain circumstances related to severe obesity.[32] Thus, an obesity CoE would likely target care for employee populations and commercially insured individuals.

FEATURES OF AN OBESITY COE

Comprehensive obesity care. Conceptually, an obesity CoE provides comprehensive care with a holistic approach that incorporates obesity treatment protocols (such as those described within the AACE/ACE guidelines) to provide the most effective care for patients. The goals are to develop a personalized treatment plan that is tailored to a patient's risk, provide support for short-term and long-term weight management success, and align incentives for all stakeholders. This approach would result in a patient receiving the most appropriate and beneficial treatment for their specific situation, while, ideally, the employer benefits from shared financial accountability. Elements of this holistic approach are already being implemented in some healthcare settings. These existing organizations are paving the way for a more integrated and comprehensive approach to obesity treatment, demonstrating the feasibility and effectiveness of such a model.

Lifestyle support. One of the key components of obesity comprehensive care is lifestyle support. This includes dietary and exercise guidance, as well as psychological support to help patients make and maintain healthy lifestyle changes. It could even provide financial counseling to help patients plan for or manage the costs associated with purchasing healthier food options or enrolling in wellness classes. The CoE could also interact with existing wellness benefits such as lifestyle management and fitness programs that employers are offering. This allows for a more holistic approach to obesity treatment, addressing not just the physical aspects of the condition, but also the behavioral factors that contribute to it.

Pharmaceutical and procedural interventions. In addition to lifestyle support, the CoE may also prescribe anti-obesity medications (AOMs) or recommend bariatric procedures, depending on the patient's individual needs and circumstances. Independent studies suggest pairing AOMs with an obesity-centric care program can lead to more patient engagement, greater weight loss, and better adherence to the medication than average.[33,34]

From an employer's perspective, AOM prescription coverage and bariatric procedures could be limited to the CoE provider network through medical network and pharmacy coverage policies. Therefore, only patients who are participating in the program and have been evaluated as appropriate would be able to receive pharmaceutical treatments for obesity. This strategy safeguards against misuse or off-label use of AOM interventions by

restricting treatment to patients who meet the clinical obesity indication requirements. Simultaneously, it combines AOM usage with continuous care from the CoE to promote lifestyle changes that contribute to greater adherence and longer-term success.

Breadth of care. A CoE for obesity requires expertise in all areas of obesity—professionals ranging from bariatricians to dieticians to sleep experts who are well-versed in the complexities of obesity and are equipped to provide comprehensive care to patients. Access to these professionals would be made easier through the CoE, given its foundation in telehealth. Patients could access expert care and ongoing support without needing to travel to a healthcare facility. This would make treatment more convenient and accessible, even for employees living in rural areas and other areas with limited access to healthcare professionals. However, recognizing that the journey to a healthier lifestyle is a long-term commitment that requires continuous encouragement and guidance, there can and should still be coordinated, in-person engagement opportunities, likely through community or patient support groups.

Integration with primary care and other specialists. Given the overlap between obesity and other conditions, coordination among providers both within and outside of the CoE is important. A CoE model should provide continuity of care with the patient's current primary and specialty providers. A coordinated care model may facilitate collaboration among healthcare providers, resulting in more efficient healthcare spend—such as not duplicating labs across multiple providers—and personalized treatment plans that consider a patient's underlying conditions (e.g., mental health). Furthermore, it enables the patient's primary care provider to be engaged in the patient's care plan, which provides additional accountability and support to the patient outside the CoE.

POTENTIAL DRAWBACKS OF AN OBESITY COE

There are potential drawbacks to consider when evaluating an obesity CoE as well. The capacity to support all acuities of obesity, including the ability to engage with patients long-term, may be a challenge. It is particularly important to ensure that certain populations, especially those without access to telehealth or technology, are not disadvantaged. To address this, an additional fee could be included to offset this disparity, such as an employer paying for necessary equipment like scales or other remote monitoring devices or providing access to computers or tablets for virtual visits. Finally, depending on the financial model and incentives associated with treatment at the CoE, it may be prudent for employers to structure their benefit designs to drive utilization to the CoE through reduced member cost sharing or other incentives. However, this could result in limiting patient choice and access to providers outside the CoE.

Operationalization of an obesity CoE

ESTABLISHING AN OBESITY COE

The formation of an obesity CoE requires defining the scope of services and care plans that will be offered, identifying clinical characteristics of patients eligible to be treated within the CoE, setting up the provider network and ensuring proper credentialing, and development of a platform tailored to the CoE.

Scope of services. One of the first steps to setting up an obesity CoE is determining the scope of services provided under the network. Ideally, the CoE network would provide comprehensive obesity care, including medical services (e.g., healthcare provider visits, bariatric procedures), prescription drugs (e.g., AOMs), coordination of care (e.g., connecting patients to specialists for comorbidities), and non-billable service (e.g., support groups). Measures for sustainable weight loss should be agreed upon and incorporated into the care plans so they can be adequately monitored and tracked over the performance period. This includes defining care pathways that outline the patient's journey from initial diagnosis and treatment to long-term maintenance. It also involves prescribing AOMs or bariatric procedures as part of a comprehensive treatment plan, when appropriate. These elements together ensure that the CoE provides a well-rounded, effective approach to obesity care.

Patient eligibility. The next step is establishing the clinical characteristics—such as BMI, body fat percentage, and presence of comorbidities—that would be necessary for an individual to qualify for care through the CoE. Treatment guidelines, such as the ACE/AACE guidelines,[18] may be considered when defining the criteria for the CoE-eligible population. The CoE should assess stratification of members based on the severity of obesity and the presence of any comorbidities, as well as consider how to manage long-term member alignment for ongoing weight maintenance support.

CoE credentialing and provider network. Once the scope of services and patient eligibility criteria has been determined, the CoE can initiate creating the provider network and ensuring proper credentialing. Providers must have or obtain state licensure to ensure they meet the necessary qualifications and standards to treat patients in each state, particularly given the nationwide telehealth-based platform of the CoE. The CoE may include providers that are employed by the CoE as well as third-party providers that are contracted to provide specific services under the CoE network, such as bariatric surgeons.

Platform development. Lastly, the CoE can develop or acquire a patient engagement telehealth platform that enables seamless patient interaction, data collection, and care coordination across the various professionals and services offered within the CoE. This could be built in-house by the CoE development team, outsourced to an external development team, or purchased from a large telehealth provider and customized to the CoE's needs. The platform should automate the specific care model for the CoE, with the care pathways integrated into the website and app.

COE AND EMPLOYER CONTRACTING

CoEs may offer various options for financial structures, member attribution methods, tracking and monitoring, and ongoing reassessments. The CoE and employers may negotiate and contract on terms for each population of interest (e.g., newly treated versus maintenance individuals). The employer could contract directly with the CoE, or the contracting could be through an insurance company, pharmacy benefit manager (PBM), or the employer's third-party administrator (TPA). The contract would reflect the agreed-upon financial model, as well as the terms for any risk-sharing or quality metrics. At a minimum, the employer would include the CoE as an in-network provider to enable patient access to the specialized provider network.

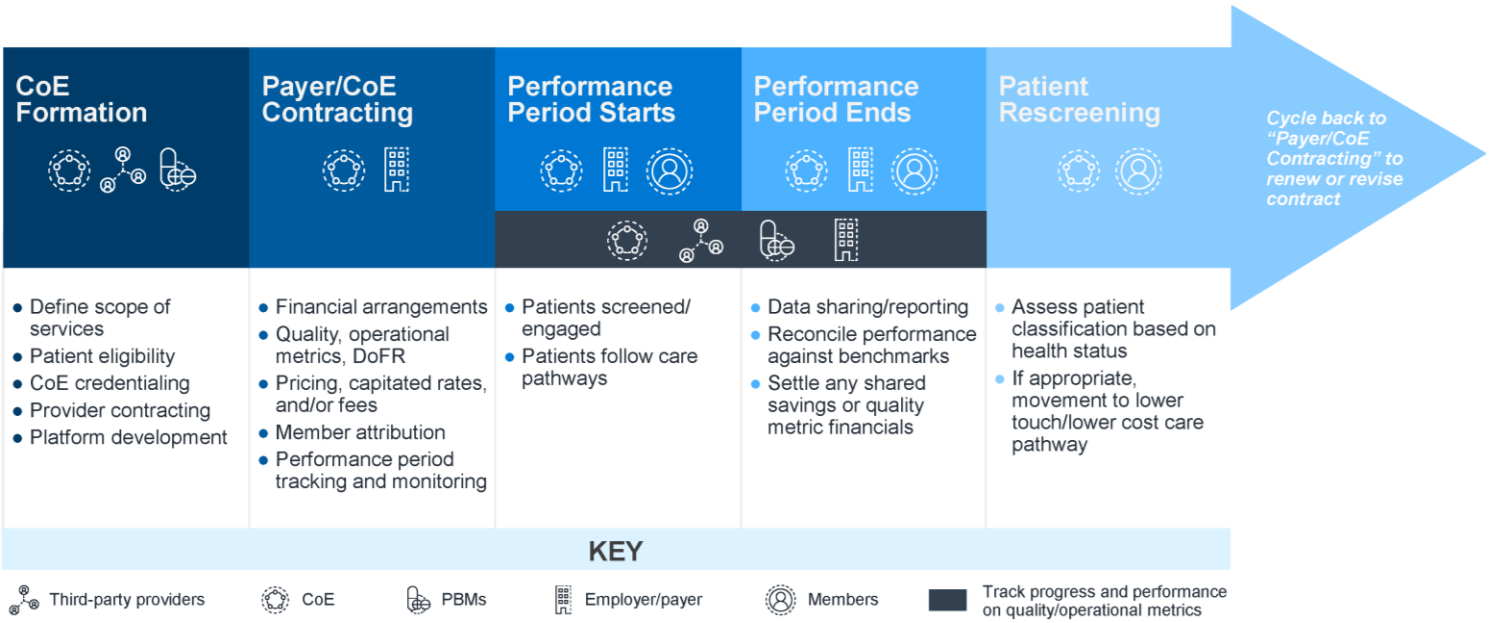
Figure 3 summarizes the timeline, key activities, and stakeholders associated with the development and operationalization of a CoE.

Financial structures and contracting. Financial structures and pricing for the CoE's services can take different forms based on the CoE's capacity for risk sharing and the employer's preferences for partnering with the CoE. The goal is to achieve a balanced and fair payment system that considers the quality, quantity, and cost of the care provided, including care and management that is not reimbursable through typical provider contracts. It is practical for the CoE to offer different financial models that align their incentives with the employers' needs to ensure both parties benefit from the partnership. Depending on the features of the chosen financial model, the CoE and employer may need to align on a division of financial responsibility (DoFR) and/or outcomes and quality metrics to ensure transparency and accountability among the contracting parties. Pricing, such as fee-for-service rates, capitated payments, bundled payments, and other fees, should also be included in the contract terms.

Setting up data-sharing pipelines and business associate agreements (BAAs) with employers, TPAs, providers, and PBMs is a key step to facilitate the efficient and secure exchange of information, promoting collaboration and coordination among all parties involved in the patients' care. Additionally, cooperation with PBMs or pharmaceutical manufacturers is crucial to ensure the appropriate management of, and access to, AOMs.

Member attribution. Attributing qualified members to the obesity CoE should be a systematic process based on objective criteria and analytics. Attribution can be performed either prospectively or retrospectively. Under a prospective approach, potential members undergo a screening process to assess their health status and determine their suitability for the program. The screening process could be triggered upon an overweight or obesity diagnosis being identified in claims data, or if an individual has diagnosed comorbidities that are typically associated with obesity, even if obesity has not directly been identified in claims data. Individuals may also choose to self-elect or may be referred by their healthcare provider to participate in the screening process. Following the screening, the eligibility of the members is determined based on specific criteria set by the CoE or employer. Once deemed eligible, members can elect to be enrolled in the CoE treatment program.

FIGURE 3: TIMELINE AND STAKEHOLDERS ASSOCIATED WITH OPERATIONALIZATION OF A COE



Under a retrospective approach, there may not be an up-front screening process for individuals who are deemed eligible to receive treatment through the CoE. Rather, any employee can choose to seek care through the obesity CoE. At the end of the performance period, the CoE-treated employee population would be assessed to identify the individuals who met certain criteria or received certain types of service. Only those individuals would be included in the attributed population for the financial modeling and outcomes or quality payment calculations.

Tracking and monitoring. Tracking progress and monitoring outcomes is a crucial aspect if quality/outcome payments or financial risk-sharing is involved. This involves the use of measurable operational and quality metrics to assess the effectiveness of the care provided, such as prevalence and incidence of obesity-related complications, percentage weight change, and overall health costs and outcomes.

There is also the potential for the CoE to collect patient-reported measures, such as patient experience, self-esteem, absenteeism, mobility, and impact on quality of life, to provide insight into indirect outcomes associated with obesity treatment. These metrics provide tangible data on the performance of the CoE, allowing for continuous improvement, refinement of the care model, and execution of outcomes contracting. They also provide valuable insights into the patients' progress, helping to guide future treatment decisions.

A recent study on measurable metrics in obesity assessed multiple obesity-related measures within 10 healthcare organizations and found that there were certain operational and quality performance measures that were useful for obesity tracking and outcomes. These measures included prevalence of overweight/obesity in the organization and within the targeted clinics, diagnosis and assessment of obesity-related complications, documentation of obesity diagnosis, percentage weight change in a 15-month period, and prescriptions for AOMs.[35]

The CDC has also published guidance on employer evaluation measures for planning of obesity prevention and control programs, which includes measurement categories such as worker productivity, healthcare costs, health outcomes, and organization changes (e.g., workplace programming).[36] It should be noted that tracking and measuring clinical outcomes over time should be normalized for the continual flux of new versus maintenance patients to limit the potential skew in overall outcomes that may result from new patients being added.

FIGURE 4: ASSESSMENT OF POTENTIAL FINANCIAL MODELS FOR AN OBESITY COE

	FFS	FFS + Quality	Shared Savings	Specialty Capitation	Full Capitation
Financial model definition	Each service has an associated payment to the provider with no link to quality or value	Each service has an associated payment and bonuses are issued to the provider for achieving quality metric goals	Total cost is compared to a benchmark and a portion of savings or losses are shared with the provider	An amount is paid to the provider to cover all services within a specialty category, shifting the risk of these services to the provider	An amount is paid to the provider to cover all services, shifting the risk of all services to the provider
Key aspects of the financial model as it applies to an obesity CoE	• FFS rate structure for obesity-related services and drugs (e.g., medical/ pharmacy claims, nutritional coaching, coordinated care) • Employers who send their members to the CoE providers pay a negotiated rate for services	• FFS rate structure for obesity-related services and drugs, supplemented with payouts associated with meeting particular quality measures, such as weight loss, patient engagement, and adherence to medication • Potentially lower FFS negotiated rates for obesity drugs and services versus FFS-only model	• CoE providers share in profit (or losses) based on total cost of care (i.e., not limited to obesity-related incurred costs) compared to benchmarks. • Shared savings measurements should be on total cost of care for there to be an opportunity for savings. The obesity CoE would take risk on total cost of care but only be responsible for managing obesity	• Capitated rate covers certain medical and drug expenditures specifically identified as being related to obesity. Incentivizes providers to not overutilize or overprescribe • Capitated rate is set in advance, potentially with premium rates varying by treatment protocol	• Capitated rate covers all medical and drug expenditures, not just those specifically identified as being related to obesity. The CoE must have large network to take risk on total cost of care • Capitated rate is set in advance, potentially with premium rates varying by treatment protocol
Assessment of financial models for an obesity CoE	**Does not mitigate volume or cost risk:** There are no outcomes-oriented risk components, nor cost containment **Easy model to implement today:** All drugs and services are paid on a fee-for-service basis	**Aligns incentives:** Provider network is oriented to obesity management and provider payments are contingent upon positive outcomes **Fairly easy model to implement today:** Requires clear outcomes/quality measures. Good precedence for this model among other condition-specific CoEs	**Accounts for total cost of care:** Shared savings/loss is possible if the CoE is willing to take risk on total cost of care, even without having a direct relationship with the provider networks managing other comorbidities **Difficult model to implement today:** Requires a clear member attribution method, multi-year tracking, and access to all medical and pharmacy claims	**Offers predictability, for a premium:** This model works for obesity CoE, but only if the PMPM rate is high enough to mitigate treatment disincentives and employers are willing to pay the higher premiums **Difficult model to implement today:** Requires a clear member attribution method, agreement on the division of financial responsibilities and premium rates	**Requires robust network of specialties and providers:** A full capitation model requires a large provider network and may limit patient choice **Difficult model to implement today:** Requires a clear member attribution method, a wide provider network, and access to all medical and pharmacy claims

Ongoing reassessments. Lastly, in a typical CoE, patients "graduate" from the CoE when they have successfully completed their treatment plan and no longer require the intensive support of the CoE. For obesity care, studies have shown that individuals with continued clinical support are more successful at maintaining their initial weight loss.[37] For this reason, an obesity CoE may elect to use an acuity-based care model that enables ongoing engagement with individuals who have met their weight loss goals and encourages continued adherence to lifestyle changes and medications (if applicable). Therefore, payments and quality measures that are tailored to short-term and long-term treatment of obesity are important for sustainability of the program. For example, the employer should not be overpaying for maintenance services, nor should the CoE be subject to quality measures that are not applicable for a treated population in the maintenance phase of treatment. The financial and quality measures must ensure that patients who require long-term care continue to receive the support they need, while also preserving the financial sustainability of the CoE.

Financial models for an obesity CoE

CoEs perform many services that replace those performed by other healthcare providers, while also performing additional services that may not be submitted or captured within the healthcare claims process. Payment contracts can be set up on a financial risk spectrum from FFS (i.e., no financial risk is shifted from the employer to the CoE) to full capitation (i.e., financial risk for total cost of care of enrolled patients is shifted to the CoE). Figure 4 describes each financial model, as well as the benefits and drawbacks for employers and providers focused on managing obesity. Of these five financial models, "FFS + Quality" and "Specialty Capitation" will be explored further in the next section, given the shared financial risk between employers and CoEs, feasibility, and likely interest of employers in such models for treatment and management of obesity.

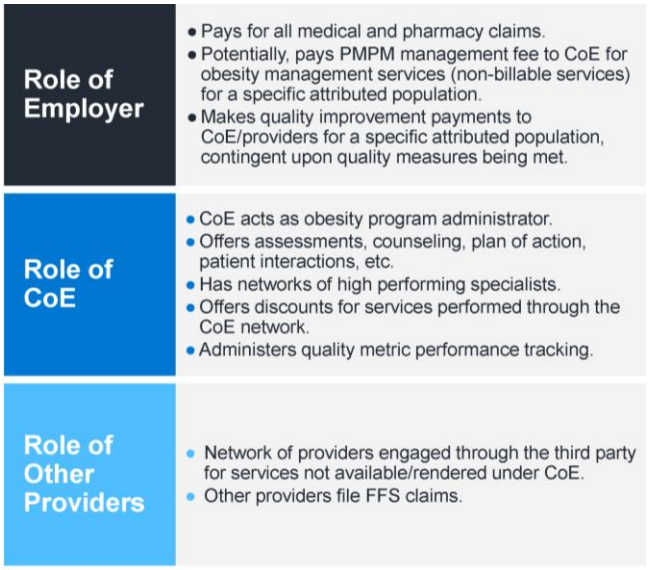
DEEPER DIVE: "FFS + QUALITY" MODEL

Figure 5 presents the role of the employer, the CoE, and other providers as it relates to the "FFS + Quality" model.

The key benefits of a "FFS + Quality" financial model are that it offers a network of physicians who are accountable for outcomes associated with obesity care and weight loss management and may also provide reduced FFS rates for obesity care services and drugs. The key drawback of this model is that employer costs increase as the volume of services, prescriptions, or adherence to AOMs increase.

The CoE and employers executing a "FFS + Quality" model must align on the fee schedule and quality payments. For instance, the obesity CoE may offer lower fees for obesity services compared to other providers, with additional quality/outcome payments made contingent on successfully meeting agreed-upon measures. Thus, providers are incentivized to meet quality/outcome goals to receive the contingent payment(s). Quality measures and outcome goals should vary depending on the population being measured, such as a newly treated population versus a maintenance population. Under the "FFS + Quality" model, the employer or its TPA will also be responsible for the monitoring and auditing of healthcare utilization. This offers another layer of oversight for the employer to confirm the CoE is not overutilizing treatment.

FIGURE 5: "FFS + QUALITY" STAKEHOLDER ROLES



DEEPER DIVE: "SPECIALTY CAPITATION" MODEL

Figure 6 presents the roles of the employer, the CoE, and other providers as they relate to the "Specialty Capitated" model.

Key benefits of a "Specialty Capitation" financial model are that it provides per-individual cost stability to the employer for the year related to obesity treatment and incentivizes providers to provide efficient care at lower costs to retain revenue from the per member per month (PMPM) capitation rate.

A drawback of this model is that the CoE providers are financially at-risk for all obesity-related care. The provider is responsible for balancing the management of healthcare costs with providing appropriate care and maintaining quality outcomes. Additionally, because direct healthcare savings from weight loss are usually linked to improvements in obesity-related comorbidities, a provider in an obesity CoE may have limited opportunities for cost savings because the healthcare cost offsets would occur outside the CoE's remit. A capitated payment model stabilizes an employer's cost exposure for an individual member, but it does not necessarily incentivize providers to drive toward particular outcomes or quality care. Therefore, it may be necessary to incorporate quality metrics into the "Specialty Capitation" model to offset the potential disincentives for providing more expensive care (when appropriate).

Furthermore, the capitation amount may be difficult to set without accounting for the mix of obesity severity levels within the employer population. Depending on the size of the employer,

experience may not be sufficient to set a credible capitation rate without using a market benchmark. Patients with more severe obesity may have a care plan that includes higher-cost AOMs and/or bariatric procedures, while patients with less severe obesity may have a care plan focused on lifestyle and nutrition management. For these reasons, the capitation rate will need to be set high enough so there is not a disincentive for providing care. However, this may make it less attractive to employers if the rate is higher compared to what is spent on obesity care today. The CoE may need to work with actuaries and other pricing experts to help determine appropriate capitation rates for each employer contract.

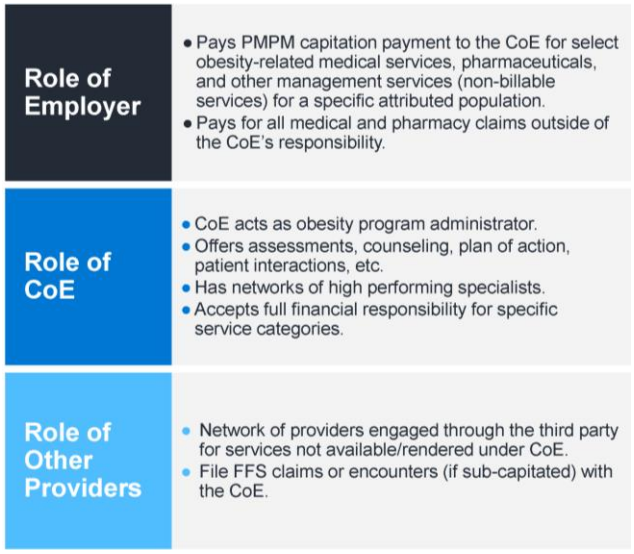
The attribution of patients and determination of appropriate capitation rates are critical in the "Specialty Capitation" model. There may be different capitation rate cells given a patient's characteristics, which would be assessed during the screening process. Furthermore, the employer and CoE must agree upon the DoFR to align on the services for which the CoE is responsible under the capitation.

Under the "Specialty Capitated" model, the employer is incentivized to drive all obesity care through the CoE. For example, if the obesity CoE is responsible for the costs of AOMs within the capitation, but an individual receives an AOM outside of the CoE, then the employer would likely be responsible for those costs. A benefit of this restriction is that the employer has confidence that obesity treatments, like AOMs, are being prescribed appropriately (i.e., no off-label use). However, this restriction may limit patient access and treatment choice. For example, if a patient with T2D was being treated with a GLP-1 drug outside of the CoE and wanted to begin treatment for obesity through the CoE, an employer might prefer that the individual switch to a GLP-1 medication indicated for obesity because the AOM costs would be included within the capitated rate. Thus, the "Specialty Capitated" model may unintentionally prefer certain GLP-1 medications.

The capitation rate needs to be high enough to ensure providers can appropriately and adequately treat each patient, but low enough that employers are willing to pay to direct all obesity care to the CoE. The employer or its TPA will be responsible for the monitoring and auditing of healthcare utilization, with the goal of verifying the CoE is appropriately using its options according to the treatment guidelines and the contracting terms to ensure the providers are not underutilizing certain treatments, such as bariatric procedures or AOMs.

Bundled payments, also known as episode-based payments, are another form of specialty capitation. A bundled payment is a fixed-price agreement for a predefined episode of care, commonly consisting of a procedure and all related services or all care for a medical condition. Bundled payments eliminate the risk to the CoE that an attributed member will receive higher-cost services early in the capitation period and then leave the program or the employer.

FIGURE 6: "SPECIALTY CAPITATION" STAKEHOLDER ROLES



Conclusion

The current landscape of obesity treatment presents several challenges, including lack of care coordination, inadequate patient support, and inconsistent coverage of treatments. This paper explored and presented key considerations for operationalizing a CoE for obesity treatment. The program should provide comprehensive, coordinated care with a goal of appropriate, efficient, and effective care. The implementation of an obesity CoE would require careful planning, including defining the scope of care, setting up data-sharing pipelines, and tracking progress and outcomes. Financially, the CoE may offer a variety of models that can shift or share the financial risk between the CoE providers and the employer. Employers that want to drive toward positive obesity outcomes may favor a financial model with payments contingent on quality or outcomes, while employers that desire predictable costs may favor a capitated pricing model. In summary, a CoE for obesity could potentially align financial and treatment incentives for obesity care, benefiting employees, employers, and healthcare providers.

.

References

1. CDC. Adult Obesity Facts. Retrieved December 15, 2023, from https://www.cdc.gov/obesity/data/adult.html.
2. Lin, X. & Li, H. (2021). Obesity: Epidemiology, pathophysiology, and therapeutics. *Front Endocrinol (Lausanne*);12. doi: 10.3389/fendo.2021.706978.
3. Swinburn, B.A., Sacks, G., Hall, K.D. et al. (2011). The global obesity pandemic: Shaped by global drivers and local environments. *Lancet*;378(9793):804-814. doi: 10.1016/S0140-6736(11)60813-1.
4. Bustillos, A., Vargas, K.G. III, & Gomero-Cuadra, R. (2014). Work productivity among adults with varied body mass index: Results from a Canadian population-based survey. *J Epidemiol Glob Health.* 201;5(2):191-199. doi: 10.1016/j.jegh.2014.08.001.
5. Cawley, J., Biener, A., Meyerhoefer, C. et al. (2021). Job absenteeism costs of obesity in the United States: National and state-level estimates. *J Occup Environ Med*;63(7):565-573. doi: 10.1097/JOM.0000000000002198.
6. Kuk, J.L., Ardern, C.I., Church, T.S. et al. (2011). Edmonton obesity staging system: Association with weight history and mortality risk. *Appl Physiol Nutr Metab*;36(4):570-576. doi: 10.1139/h11-058.
7. Bailey-Davis, L., Wood, G.C., Benotti, P. et al. Impact of sustained weight loss on cardiometabolic outcomes. *Am J Cardiol*. 2022;162:66-72. doi: 10.1016/j.amjcard.2021.09.018.
8. Haase, C.L., Lopes, S., Olsen, A.H., Satylganova, A., Schnecke, V., & McEwan, P. (2021). Weight loss and risk reduction of obesity-related outcomes in 0.5 million people: Evidence from a UK primary care database. *Int J Obes (Lond)*;45(6):1249-1258. doi: 10.1038/s41366-021-00788-4.
9. Cefalu, W.T., Bray, G.A., Home, P.D. et al. (2015). Advances in the science, treatment, and prevention of the disease of obesity: Reflections from a diabetes care editors' expert forum. *Diabetes Care*;38(8):1567-1582. doi: 10.2337/dc15-1081.
10. Phelan, S.M., Burgess, D.J., Yeazel, M.W., Hellerstedt, W.L., Griffin, J.M., & van Ryn, M. (2015). Impact of weight bias and stigma on quality of care and outcomes for patients with obesity. *Obes Rev*;16(4):319-326. doi: 10.1111/obr.12266.
11. International Foundation of Employee Benefit Plans. Employee Benefits Survey: 2022 Results. Retrieved December 15, 2023, from https://www.ifebp.org/store/employee-benefits-survey/Pages/default.aspx.
12. Nasdaq (October 9, 2023). GLP-1 Coverage in Employer Plans Could Nearly Double in 2024. Retrieved December 15, 2023, from https://www.nasdaq.com/press-release/glp-1-coverage-in-employer-plans-could-nearly-double-in-2024-2023-10-09.
13. Khemlani, A. (August 22, 2023). Large employers split on covering GLP-1 drugs for weight loss: Survey. Yahoo Finance. Retrieved December 15, 2023, from https://finance.yahoo.com/news/large-employers-split-on-covering-glp-1-drugs-for-weight-loss-survey-140004887.html.
14. Patel, M.S., Asch, D.A., Troxel, A.B. et al. (2016). Premium-based financial incentives did not promote workplace weight loss in a 2013-15 study. *Health Aff (Millwood)*;35(1):71-79. doi:10.1377/hlthaff.2015.0945.
15. Ro. Get prescription weight loss medication online. Retrieved December 15, 2023, from https://ro.co/weight-loss/.
16. Lopatto E. (October 2, 2023). Who wins when telehealth companies push weight loss drugs? The Verge. Retrieved December 15, 2023, from https://www.theverge.com/23878992/ro-ozempic-subway-ads-telehealth-weight-loss-drugs.
17. University of Michigan Health Frankel Cardiovascular Center. Comprehensive Complex Coronary Disease. Retrieved December 15, 2023, from https://www.umcvc.org/conditions-treatments/comprehensive-complex-coronary-disease.
18. Garvey, W.T., Mechanick, J.I., Brett, E.M. et al. (July 2016). American Association of Clinical Endocrinologists & American College of Endocrinology Comprehensive Clinical Practice Guidelines for Medical Care of Patients With Obesity. *Endocr Pract*.;22(3). Retrieved December 15, 2023, from https://pro.aace.com/files/obesity/final-appendix.pdf.
19. Mechanick, J.I., Apovian, C., Brethauer, S. et al. (2019). Clinical practice guidelines for the perioperative nutrition, metabolic, and nonsurgical support of patients undergoing bariatric procedures – 2019 update: Cosponsored by the American Association of Clinical Endocrinologists/American College of Endocrinology, the Obesity Society, American Society for Metabolic and Bariatric Surgery, Obesity Medicine Association, and American Society of Anesthesiologists. *Endocr Pract*;25(12). doi: 10.4158/GL-2019-0406.
20. Cawley, J., Biener, A., Meyerhoefer, C. et al. (2021). Direct medical costs of obesity in the United States and the most populous states. *J Manag Care Spec Pharm*;27(3):354-366. doi: 10.18553/jmcp.2021.20410.
21. Ward, Z.J., Bleich, S.N., Long, M.W., & Gortmaker, S.L. (2021). Association of body mass index with healthcare expenditures in the United States by age and sex. *PLoS One*;16(3). doi: 10.1371/journal.pone.0247307.
22. Thorpe, K., Toles, A., Shah, B., Schneider, J., & Bravata, D.M. (2021). Weight loss-associated decreases in medical care expenditures for commercially insured patients with chronic conditions. *J Occup Environ Med*;63(10):847-851. doi: 10.1097/JOM.0000000000002296.
23. Gates, D.M., Succop, P., Brehm, B.J., Gillespie, G.L., & Sommers, B.D. (2008). Obesity and presenteeism: The impact of body mass index on workplace productivity. *J Occup Environ Med*;50(1):39-45. doi: 10.1097/JOM.0b013e31815d8db2.

24. AHIP (May 24, 2023). New survey: Consumers say comprehensive employer-provided coverage vital to their financial peace of mind. Retrieved December 15, 2023, from https://www.ahip.org/news/press-releases/new-survey-consumers-say-comprehensive-employer-provided-coverage-vital-to-their-financial-peace-of-mind.
25. Marshall, C. (2020). Analysis of a comprehensive wellness program's impact on job satisfaction in the workplace. *IHR*;34(2):221-241. doi: 10.1108/IHR-05-2020-0014.
26. Memorial Sloan Kettering Cancer Center. For Health Plans. Retrieved December 15, 2023, from https://www.mskcc.org/mskdirect/health-plans.
27. Virgina Mason Medical Center (March 22, 2016). State picks Virgina Mason as center of excellence for total joint replacement. News Wise. Retrieved December 15, 2023, from https://www.newswise.com/articles/state-picks-virginia-mason-as-center-of-excellence-for-total-joint-replacement.
28. Panoramic Health. Treatment with a 360° view of your health. Retrieved December 15, 2023, from https://panoramichealth.com/patients/.
29. UMass Memorial Health. Diabetes. Retrieved December 15, 2023, from https://www.ummhealth.org/umass-memorial-medical-center/diabetes.
30. Johns Hopkins Medicine. The Johns Hopkins Precision Medicine Center of Excellence for Chronic Obstructive Pulmonary Disease (COPD). Retrieved December 15, 2023, from https://www.hopkinsmedicine.org/inhealth/copd.
31. Centers for Medicare and Medicaid Services (April 19, 2006). Part D drugs/Part D excluded drugs. Retrieved December 15, 2023, from https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/partddrugspartdexcludeddrugs.pdf.
32. Medicare. Bariatric surgery. Retrieved December 15, 2023, from https://www.medicare.gov/coverage/bariatric-surgery.
33. Pantalone, K.M., Smolarz, B.G., Ramasamy, A. et al. (2021). Effectiveness of combining anti-obesity medication with an employer-based weight management program for treatment of obesity: A randomized clinical trial. *JAMA Netw Open*;4(7). doi: 10.1001/jamanetworkopen.2021.16595.
34. Leach, J., Chodroff, M., Qiu, Y. et al. (July 11, 2023). Real-world analysis of glucagon-like peptide-1 agonist (GLP-1a) obesity treatment one year cost-effectiveness and therapy adherence. Prime Therapeutics. Retrieved December 15, 2023, from https://www.primetherapeutics.com/wp-content/uploads/2023/07/GLP-1a-obesity-treatment-1st-year-cost-effectiveness-study-abstract-FINAL-7-11.pdf.
35. Ciemins, E., Joshi, V., Horn, D., Nadglowski, J., Ramasamy, A., & Cuddeback, J. (2021). Measuring what matters: Beyond quality performance measures in caring for adults with obesity. *Popul Health Manag*;24(4):482-491. doi: 10.1089/pop.2020.0109.
36. CDC. Obesity evaluation measures. Retrieved December 15, 2023, from https://www.cdc.gov/workplacehealthpromotion/health-strategies/obesity/evaluation-measures/index.html.
37. Lenoir, L., Maillot, M., Guilbot, A., & Ritz P. (2015). Primary care weight loss maintenance with behavioral nutrition: An observational study. *Obesity (Silver Spring)*;23(9):1771–1777. doi: 10.1002/oby.21157.

Limitations

Milliman was engaged by Eli Lilly to support exploring the concept of an obesity CoE. This paper was supported by research and Milliman subject matter experts familiar with disease management programs, CoEs, and risk-sharing models. This white paper outlines typical and/or the most relevant types of programs that may be applicable to an obesity CoE; it is not intended to be a comprehensive study of every type of program or model available.

While this report provides a guide for operationalizing a center of excellence, entities interested in creating a CoE model for obesity should engage with the appropriate professionals to address specific financial and operational nuances. The comprehensive obesity CoE model described in this white paper, to our knowledge, is not yet in existence. Therefore, the process and financial models outlined here are intended to provide thought leadership as a conceptual solution for obesity treatment. Actual experience for operationalizing an obesity CoE may vary from what has been described herein.

Guidelines issued by the American Academy of Actuaries require actuaries to include their professional qualifications in all actuarial communications. Austin Barrington and Jessica Naber are members of the American Academy of Actuaries and meet the qualification standards for authoring this report.

Milliman

Milliman is among the world's largest providers of actuarial, risk management, and technology solutions. Our consulting and advanced analytics capabilities encompass healthcare, property & casualty insurance, life insurance and financial services, and employee benefits. Founded in 1947, Milliman is an independent firm with offices in major cities around the globe.

milliman.com

CONTACT

Jessica Naber
jessica.naber@milliman.com

Austin Barrington
austin.barrington@milliman.com

Bryce Platt
bryce.platt@milliman.com

MILLIMAN WHITE PAPER

Payer strategies for GLP-1 medications for weight loss

Helping payers understand the landscape, develop a coverage strategy, and minimize waste

AJ Ally, RPh, MBA
Deana Bell, FSA, MAAA
Melody Craff, PhD, MBA, MD, MS, MA, FAHM
Jeffrey Garbe, RPh
Mark Gruenhaupt, RPh
Peter Heinen, FSA, MAAA
Ellyn M. Russo, MS

Milliman

Approximately 42% of the U.S. population has obesity[1] and, with more than 200 diseases associated with this condition, the demand for weight loss solutions has never been higher. The glucagon-like peptide-1 (GLP-1) receptor agonist drug class, which has been clinically proven to effectively manage type 2 diabetes,[2] is also proving to be highly effective for the treatment of obesity.[3] Many believe it has the potential to meet this growing need.

While GLP-1 medications are costly, they have the potential to decrease medical cost if treated patients achieve sustained weight control[4] in combination with diet and exercise. Furthermore, these medications have now been shown to reduce the risk of major adverse cardiovascular events.[5] They also have potential gastrointestinal (GI) side effects, which may contribute to low medication adherence and early discontinuation of therapy. In a recent study, more than 68% of patients did not maintain GLP-1 therapy for 12 months.[6] Based on these published results, Milliman estimates that a payer with similar discontinuation rates may experience 26% waste in drug spend.

To properly manage these opportunities and challenges, there are key actions payers should take related to coverage of GLP-1s for weight loss, including: evaluating coverage of obesity medications, ensuring appropriate utilization to address adherence and persistency issues, developing a patient engagement strategy to ensure optimal value, and evaluating pharmacy supply chain contracts to ensure optimal pricing. Ultimately, a comprehensive weight loss and therapy management approach is needed to increase treatment success and improve patient wellness.

[1] Centers for Disease Control and Prevention. FastStats: Obesity and Overweight. Retrieved August 17, 2023, from https://www.cdc.gov/nchs/fastats/obesity-overweight.htm.

[2] Nauck, M.A. et al. (October 14, 2020). GLP-1 Receptor Agonists in the Treatment of Type 2 Diabetes – State-of-the-Art. Mol Metab. Retrieved August 17, 2023, from https://pubmed.ncbi.nlm.nih.gov/33068776/.

[3] Jensterle, M. et al. (May 3, 2022). Efficacy of GLP-1 RA Approved for Weight Management in Patients With or Without Diabetes: A Narrative Review. Adv Ther. Retrieved August 17, 2023, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9063254.

[4] Cawley, J. et al. (July 2015). Savings in Medical Expenditures Associated With Reductions in Body Mass Index Among U.S. Adults With Obesity, by Diabetes Status. Pharmacoeconomics. Retrieved August 17, 2023, from https://pubmed.ncbi.nlm.nih.gov/25381647/.

[5] Novo Nordisk (August 8, 2023). Semaglutide 2.4 mg Reduces the Risk of Major Adverse Cardiovascular Events by 20% in Adults With Overweight or Obesity in the SELECT Trial. News release. Retrieved August 17, 2023, from https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-ir-materials/news-details.html?id=166301.

[6] Leach, J. et al. (July 11, 2023). Real-World Analysis of Glucagon-Like Peptide-1 Agonist (GLP-1a) Obesity Treatment One Year Cost-Effectiveness and Therapy Adherence. Prime Therapeutics and MagellanRx. Retrieved August 17, 2023, from https://www.primetherapeutics.com/wp-content/uploads/2023/07/GLP-1a-obesity-treatment-1st-year-cost-effectiveness-study-abstract-FINAL-7-11.pdf.

Over the past year, there has been a dramatic increase in utilization of the GLP-1 receptor agonist drug class. This class of drugs includes recently approved injectables that have demonstrated a much greater efficacy in weight loss, with a fast onset, and low incidence of serious side effects (requiring warnings and precautions in labeling). Figure 1 summarizes the select GLP-1 receptor agonist medications with weight loss indication and their reported effect on body weight.

Current medications

FIGURE 1: SUMMARY OF GLP-1 MEDICATIONS FOR WEIGHT LOSS

MEDICATION	FDA APPROVAL DATE FOR CHRONIC WEIGHT MANAGEMENT	AVERAGE % CHANGE IN BODY WEIGHT (RANGE)	ADDITIONAL NOTES
Saxenda (liraglutide)	12/23/2014	6.7% to 9.2%[7]	Liraglutide was approved for the treatment of type 2 diabetes in 2010 under the brand name Victoza. Saxenda is available in higher doses than Victoza.
Wegovy (semaglutide)	6/4/2021	9.6% to 16%[8]	Semaglutide was approved for the treatment of type 2 diabetes in 2017 under the brand name Ozempic. Wegovy is available in higher doses than Ozempic.
Mounjaro (tirzepatide)	PDUFA date in Q4 2023	15.7% to 22.5%[9,10]	Approved for the treatment of type 2 diabetes in 2022.

Note: Average percentage change in body weight based on maximum dose. The Prescription Drug User Fee Act (PDUFA) date is at the end of the review period after a drug is filed with the FDA for approval.

Additional medications in this class (Adlyxin, Bydureon, Byetta, Rybelsus, and Trulicity) were not included in this review due to limited use for and effect on weight loss.[11]

The estimated average annual wholesale acquisition cost (WAC) for GLP-1 drug class products that are utilized for weight loss ranges from $12,200 to $17,600.[12] Three other medications (Qsymia, Contrave, and Xenical) are currently approved for chronic weight management, with the WAC ranging from $2,300 to $9,200 annually.

Clinical distinction

GLP-1 drugs mimic the action of naturally occurring GLP-1 hormone in the intestinal tract. One of GLP-1's mechanisms of action is increasing the sense of satiety, the feeling of being sated or full, by slowing down the rate at which food leaves the stomach. GLP-1s also impact the brain's perception of fullness, leading people to reduce food intake.[13]

The first GLP-1 drugs were originally studied and approved to treat type 2 diabetes, showing effectiveness at lowering blood sugar levels and A1C (a blood test showing average blood sugar over the prior two to three months). It became evident during drug trials that some of the GLP-1 drugs were also causing significant weight loss in a large portion of the study population, which led to specific drug trials for that indication. GLP-1 drugs approved for weight loss are all injectable products, dosed either daily or weekly. Once daily Rybelsus (semaglutide) is the sole oral

[7] Novo Nordisk (April 2023). Saxenda prescribing information. Retrieved August 17, 2023, from https://www.novo-pi.com/saxenda.pdf.

[8] Novo Nordisk (August 2022). Wegovy prescribing information. Retrieved August 17, 2023, from https://www.novo-pi.com/wegovy.pdf.

[9] Eli Lilly and Company (June 24, 2023). Lilly's SURMOUNT-2 Results Published in The Lancet Show Tirzepatide Achieved a Mean Weight Reduction of 15.7% at the Highest Dose (15 mg) in Adults With Obesity or Overweight and Type 2 Diabetes. News release. Retrieved August 17, 2023, from https://investor.lilly.com/news-releases/news-release-details/lillys-surmount-2-results-published-lancet-show-tirzepatide.

[10] Eli Lilly and Company (April 28, 2022). Lilly's Tirzepatide Delivered Up to 22.5% Weight Loss in Adults With Obesity or Overweight in SURMOUNT-1. News release. Retrieved August 17, 2023, from https://investor.lilly.com/node/47141/pdf.

[11] Trujillo, J.M. et al. (March 9, 2021). GLP-1 Receptor Agonists: An Updated Review of Head-to-Head Clinical Studies. Ther Adv Endocrinol Metab. Retrieved August 17, 2023, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7953228/.

[12] Based on 2023 WAC prices accessed from the Texas Health and Human Services prescription drug price disclosure program. Retrieved August 17, 2023, from https://www.dshs.texas.gov/prescription-drug-price-disclosure-program/data-overview. Includes Wegovy, Saxenda, Ozempic, Victoza, and Mounjaro. Additional medications in this class (Adlyxin, Bydureon, Byetta, Rybelsus, and Trulicity) were not included in this review due to limited use for and effect on weight loss. Annual cost based on WAC does not factor in any manufacturer rebates or discounts. Annual is defined as 365 days of therapy.

[13] Ard, J. et al. (May 11, 2021). Weight Loss and Maintenance Related to the Mechanism of Action of Glucagon-Like Peptide 1 Receptor Agonists. Adv Ther. Retrieved August 17, 2023, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8189979/.

GLP-1 product currently on the market. It is only indicated for the treatment of type 2 diabetes, but it is being studied for weight loss at significantly higher doses than those indicated for treatment of diabetes. Initial results were recently released and show weight loss comparable to the injectable versions of the drug.[14]

The most common side effects of this drug class involve the digestive system. Incidence rates are dependent on the medication and dose, but the most frequent adverse reactions are nausea (31%-44%), diarrhea (21%-32%), vomiting (12%-25%), and constipation (12%-23%).[15,16,17,18] To minimize the initial side effects of these products, they require an initial dose escalation period (stepwise escalation in dosage to achieve therapeutic levels). For example, to reach the full maintenance dose, Saxenda and Victoza have the shortest dose escalation period (four escalations over 28 days), while Ozempic and Wegovy have four escalations over a 16-week period, and Mounjaro has five escalations over a 20-week period. Some potentially serious but much rarer side effects include acute pancreatitis, thyroid tumors, acute kidney injury, heart rate increases, and acute gallbladder disease.[15,16,17,18]

Noticeable weight loss can often be seen in a few weeks after starting the drugs, with peak weight loss typically seen after approximately 12 to 18 months on therapy. Weight loss is typically maintained until therapy is discontinued, meaning that sustained weight loss may require long-term therapy. One drug manufacturer's study showed that patients regained two-thirds of their weight back after being off the drug for a year.[19] These medications have been shown to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes,[20] but the potential long-term effects (positive or negative) of taking these medications for weight loss for an extended period of time remains unclear. There are multiple ongoing studies being conducted to measure these impacts, with the first trial results expected later this year.[21]

Media attention and market demand

In 2021 alone, Americans spent an estimated $72.6 billion on weight loss (diet programs, surgeries, drugs, supplements, apps, etc.).[22] Numerous diets, drugs, food plans, and other programs for weight loss have shown promise in the past but have not been able to materially slow the rising rate of obesity. GLP-1 medications are the latest entry in this search for an effective and lasting weight loss method, generating significant buzz, especially across social media. Adding to the published outcomes of the effects of this drug class are celebrity testimonials, a dramatic spike in social media activity (the hashtag #mounjaro has over 600 million views on TikTok), and numerous national media stories that share information about the quick and dramatic weight loss reported by some users of these products. Advertising and promotion by pharmaceutical manufacturers and intense marketing by weight loss and telehealth companies offering the products as part of their weight loss services has also increased significantly in the past year.[23]

---

[14] Novo Nordisk (May 22, 2023). Oral Semaglutide 50 mg Achieved 15.1% Weight Loss (17.4% if all people adhered to treatment) in Adults With Obesity or Overweight in the OASIS 1 Trial. News release. Retrieved August 17, 2023, from https://www.novonordisk.com/news-and-media/news-and-ir-materials/news-details.html?id=166110.

[15] Liu, L. et al. (December 7, 2022). Association Between Different GLP-1 Receptor Agonists and Gastrointestinal Adverse Reactions: A Real-World Disproportionality Study Based on FDA Adverse Event Reporting System Database. Front. Endocrinol. Retrieved August 17, 2023, from https://www.frontiersin.org/articles/10.3389/fendo.2022.1043789/full.

[16] Jastreboff, A. M. et al. (July 21, 2022). Tirzepatide Once Weekly for the Treatment of Obesity. N Engl J Med. Retrieved August 17, 2023, from https://www.nejm.org/doi/full/10.1056/NEJMoa2206038.

[17] Wegovy prescribing information, op cit.

[18] Saxenda prescribing information, op cit.

[19] Wilding, J.P.H. et al. (April 19, 2022). Weight Regain and Cardiometabolic Effects After Withdrawal of Semaglutide: The STEP 1 Trial Extension. Diabetes, Obesity and Metabolism. Retrieved August 17, 2023, from https://dom-pubs.onlinelibrary.wiley.com/doi/10.1111/dom.14725.

[20] Sattar, N. et al. (August 20, 2021). Cardiovascular, Mortality, and Kidney Outcomes With GLP-1 Receptor Agonists in Patients With Type 2 Diabetes: A Systematic Review and Meta-Analysis of Randomized Trials. The Lancet. Retrieved August 17, 2023, from https://www.thelancet.com/journals/landia/article/PIIS2213-8587(21)00203-5/fulltext.

[21] Novo Nordisk, loc. cit.

[22] Marketdata LLC. The U.S. Weight Loss Market: 2022 Status Report & Forecast (March 2022). Retrieved August 23, 2023, from https://www.researchandmarkets.com/reports/5556414/the-u-s-weight-loss-market-2022-status-report.

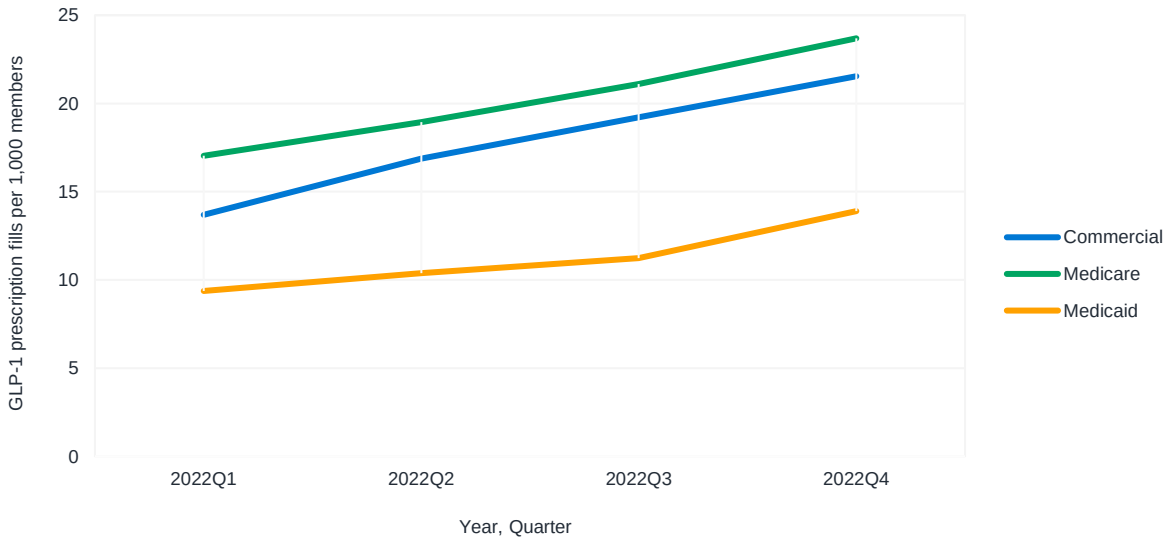
[23] Landi, H. (May 9, 2023). Digital Health Companies Making a Long-Term Play to Tackle Metabolic Health Amid Hype Over $100B Weight Loss Drug Market. Fierce Healthcare. Retrieved August 17, 2023, from https://www.fiercehealthcare.com/health-tech/telehealth-companies-target-100b-weight-loss-drug-market-patients-grapple-access-costs.

All these factors have combined to create significant demand for these products. The result has been a shortage of products for patients with diabetes, as well as for those seeking to lose weight. Compounding pharmacies have even started mixing the injectable product to fill the gap and offer a lower-cost prescription (reported to be as low as $300 per patient per month).[24] At least four states[25] have taken action to curb the compounding of semaglutide over safety concerns, and the manufacturer of Ozempic and Wegovy recently brought suit to challenge this practice with considerations for patent protection and compounding regulations.

Patients have also been attempting to source these products from other countries, such as Canada, where there is reportedly a significant outflow of thousands of doses of Ozempic each month, so much so that the Canadian Health Minister is exploring ways to prevent "mass exportation" of these products.[26]

Figure 2 shows quarterly utilization for GLP-1s for the most recent 12-month period. From Q1 to Q4 2022, there was an increase in GLP-1 utilization across core sources of health benefits coverage—57% for the commercial market, 39% for Medicare (includes Medicare prescription drug plans [PDPs] and Medicare Advantage), and 48% for Medicaid.

FIGURE 2: GLP-1 PRESCRIPTION FILLS PER 1,000 CONTINUOUSLY ENROLLED MEMBERS AGED 12 YEARS AND OLDER FOR MOST RECENT 12-MONTH PERIOD BY QUARTER



Source: Analysis of utilization for liraglutide, semaglutide, and tirzepatide using Milliman MedInsight® Emerging Experience research data.
Note: Medicare results are only for a diabetes indication as Medicare does not cover medications for obesity and weight loss indications.

[24] Landsverk, G. (February 2, 2023). Shortages of a "Game Changer" Weight-Loss Drug Are Driving People to Buy Potentially Risky Knockoff Versions. Insider. Retrieved August 17, 2023, from https://www.insider.com/buy-compounded-semaglutide-online-risks-wegovy-ozempic-2023-1.

[25] Ibid.

[26] The Canadian Press (April 12, 2023). Canada's Health Minister Calls Mass Exports of Ozempic to U.S. an "Outrageous" Abuse. Toronto Star. Retrieved August 17, 2023, from https://www.thestar.com/politics/2023/04/12/canadas-health-minister-calls-mass-exports-of-ozempic-to-us-an-outrageous-abuse.html.

Current coverage status by U.S. market segments

In 2013 the American Medical Association (AMA) officially recognized obesity as a complex chronic disease.[27] However, there is stigma around obesity and many still see it as strictly a behavioral problem rather than a disease with behavioral components that can be medically managed and prevented.[28] In addition, older anti-obesity medications have either shown limited effectiveness or significant side effects. That combination of factors has led many government payers and some commercial payers to exclude weight loss medications from coverage.

COMMERCIAL INSURERS INCLUDING EMPLOYER-SPONSORED PLANS

Most fully insured commercial payers cover GLP-1 medications for weight loss but typically with coverage restrictions (patient qualification) and step therapy. Of the 17 largest insurers in the United States, 11 have a public coverage policy detailing coverage for GLP-1 medications for weight management, with nine of the 11 having restrictions beyond the U.S. Food and Drug Administration (FDA) label.[29] Employer-sponsored (self-funded) coverage of weight loss drugs has ranged from 33% to 63% of employer groups, based on recent data from pharmacy benefit managers (PBMs), with up to 80% of those groups covering the GLP-1s for weight loss applying prior authorization to control utilization.[30]

HEALTH EXCHANGE PLANS

The Patient Protection and Affordable Care Act (ACA) does not consider weight loss medications "essential benefits" and therefore does not require plan sponsors to cover GLP-1 drugs for weight loss or obesity. There are requirements for plans to offer diet counseling and obesity screening and counseling as part of preventive care benefits without cost sharing to the beneficiary, but those service categories do not include these new medications or older treatments for weight loss and obesity.

The U.S. Preventive Services Task Force (USPSTF) currently has a draft research plan out for public comment regarding "Weight Loss to Prevent Obesity-Related Morbidity and Mortality in Adults: Interventions." If GLP-1s are graded as an A or B recommendation from the USPSTF as a result of this study, then coverage for these products would be mandatory as a preventive service, with plans required to provide them at no cost sharing for patients.[31]

TRADITIONAL MEDICARE, MEDICARE ADVANTAGE AND PART D (MA-PD), AND PDPS

Obesity and weight loss medications are excluded from coverage in Medicare Part B and Part D by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. However, the versions of these medications that are indicated for diabetes (e.g., Ozempic, Victoza, and Mounjaro), are required to be covered at a class level for treatment of diabetes under Medicare Part D.

As shown in Figure 2 above, Medicare Part D plans have also recently seen a dramatic increase in the prescriptions for these medications, despite the fact that they are only covered for treatment in diabetes. Much of this increase can be attributed to an increase in the overall use of GLP-1s as first line therapy in diabetes, driven by label expansions to help prevent cardiovascular complications from diabetes and the potential for weight loss in diabetics, along with updated guidelines from the American Diabetes Association related to treating diabetics with cardiovascular disease.[32]

---

[27] Kyle, T.K., Dhurandhar, E.J., & Allison, D.B. (September 2016). Regarding Obesity as a Disease: Evolving Policies and Their Implications. Endocrinol Metab Clin North Am. Retrieved August 17, 2023, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4988332/.

[28] Puhl, R.M. & Heuer, C.A. (September 6, 2012). The Stigma of Obesity: A Review and Update. Obesity. Retrieved August 17, 2023, from https://onlinelibrary.wiley.com/doi/full/10.1038/oby.2008.636.

[29] Tepper, N. (May 16, 2023). Insurers, PBMs Restrict Access to Weight Loss Drugs as Demand Soars. Modern Healthcare. Retrieved August 17, 2023, from https://www.modernhealthcare.com/insurance/pbms-insurers-ozempic-wegovy-weight-loss-drug-access-cigna-centene (subscription required).

[30] Welliver, S., Susie, C., & Binkely, D. (March 16, 2023). #Ozempic: TikTok Fad or Weight Management Disruptor?. Mercer. Retrieved August 17, 2023, from https://www.mercer.com/en-us/insights/us-health-news/ozempic-tiktock-fad-or-weight-management-disruptor/.

[31] U.S. Preventive Services Task Force (May 18, 2023). Weight Loss to Prevent Obesity-Related Morbidity and Mortality in Adults: Interventions. Retrieved August 17, 2023, from https://www.uspreventiveservicestaskforce.org/uspstf/document/draft-research-plan/weight-loss-prevent-obesity-related-morbidity-mortality.

[32] American Diabetes Association Professional Practice Committee (December 16, 2021). 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes—2022. Diabetes Care 2022. Retrieved August 17, 2023, from https://diabetesjournals.org/care/article/45/Supplement_1/S125/138908/9-Pharmacologic-Approaches-to-Glycemic-Treatment.

With this increase, utilization management strategies that are within the bounds of Centers for Medicare and Medicaid Services (CMS) rules, such as prior authorization to validate diagnosis, are being considered by plan sponsors to limit the utilization to those indications covered by Medicare. Some plan sponsors are concerned about the potential future cost of these medications if they are covered for weight management. According to one study, it would cost taxpayers more than $26 billion annually if just 10% of eligible patients got these new drugs.[33] More studies are needed to better assess the potential impact and benefit of covering obesity and weight loss medications using real-world data.

Recently, several advocacy groups have been asking Congress and the Biden administration to allow coverage of weight loss medications.[34] Three potential routes to coverage would be Congressional action,[35] an innovation program proposed by the presidential administration, or having CMS redefine these medications for treatment of a chronic disease (obesity) instead of "agents when used for weight loss."[36]

MEDICAID

Medicaid coverage of GLP-1 products varies by state, with multiple states not providing coverage for the products indicated for weight loss. Most GLP-1 coverage under Medicaid is for GLP-1 products with the diabetes indications only, and it is common for these products to require a prior authorization to apply clinical criteria under Medicaid.

Importance of medication adherence and persistency

Research shows that semaglutide and liraglutide must be taken consistently and long-term to achieve and maintain weight loss benefits.[37] Patients who discontinue use after a few initial doses or are inconsistent with their dosing will likely not see any material health benefits and could incur waste in prescription benefit dollars.

A recent real-world analysis of GLP-1 agonist obesity treatment conducted by two pharmacy benefit managers (PBMs) found that 32% of members on treatment were persistent at one year, and 27% of those remaining on therapy were adherent during the following year.[38] Adherence is measured using proportion of days covered (PDC); the number of days' supply a drug is dispensed divided by the number of days the prescription is in the patient's possession.[39] Optimal adherence is defined as a PDC of 80% or higher.[40] Persistence, a leading indicator of adherence, represents the time (e.g., days, months, and years) over which a patient continues the treatment.

While not detailed in the aforementioned PBM study, there are several factors that may be contributing to early discontinuation of treatment, including clinical side effects, cost barriers, and inefficient or inconvenient prior authorization processes. Due to the significant rate of therapy drop-offs indicated by the study, payers may want to develop a comprehensive plan to encourage adherence. Wegovy and Saxenda are currently indicated for patients with an initial body mass index (BMI) of 30 kg/m2 or greater (obese) or 27 kg/m2 or greater (overweight), in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia), where the greatest impact to overall health improvement can be realized.

[33] Lapid, N. (March 11, 2023). Economists Warn of Costs if Medicare Covers New Obesity Drugs. Reuters. Retrieved August 17, 2023, from https://www.reuters.com/world/us/economists-warn-costs-if-us-medicare-covers-new-obesity-drugs-2023-03-11.

[34] Whyte, L.E. (April 24, 2023). Weight-Loss Drugmakers Lobby for Medicare Coverage. Wall Street Journal. Retrieved August 17, 2023, from: https://www.wsj.com/articles/weight-loss-drugmakers-lobby-for-medicare-coverage-69188697.

[35] Congress.gov (2021-2022). S.596 – Treat and Reduce Obesity Act of 2021. Retrieved August 17, 2023, from https://www.congress.gov/bill/117th-congress/senate-bill/596.

[36] Neuman, T. & Cubanski, J. (May 18, 2023). What Could New Anti-Obesity Drugs Mean for Medicare? Kaiser Family Foundation Policy Watch. Retrieved August 17, 2023, from https://www.kff.org/policy-watch/what-could-new-anti-obesity-drugs-mean-for-medicare/.

[37] Wilding, J.P.H. et al., op cit.

[38] Leach, J. et al., op cit.

Potential for prescription benefit spend waste

Due to the high cost of GLP-1s and the challenges in maintaining optimal medication adherence, it is important to acknowledge the potential for added waste in the system and ultimately for payers. Figure 3 illustrates the potential for significant financial waste if patients do not sustain therapy for at least 12 months.

FIGURE 3: ILLUSTRATION OF MEDICATION WASTE FOR 100,000 ENROLLEES

CALCULATION COMPONENT		VALUE	SOURCE
Number of enrollees for a commercial payer	A	100,000	Assumption
% with obesity	B	40.9%	See notes
Enrollees with obesity	C	40,900	= A x B
Average annual net cost to payer for Wegovy, Saxenda	D	$10,100	See notes
% of enrollees with obesity that start therapy	E	10%	Modeling assumption
Number of enrollees with obesity that start therapy	F	4,090	= C x E
% patients who drop off therapy after 12 months*	G	68%	See notes
Number of patients who drop off therapy	H	2,781	= F x G
Cost of wasted drugs for 2 months**	I	$1,683	= D x (2/12)
Total wasted medication cost	J	$4,681,687	= H x I
Total cost for non-drop-off patients***	K	$13,218,880	= D x F x (1 - G)
Total medication cost	L	$17,900,567	= J + K
% wasted spend		26%	= J / L

Notes: Assumes a typical commercial payer with 100,000 enrollees (A), and that 40.9% of insured adults have obesity (B).[41]

Assumes formulary coverage and estimated based on wholesale acquisition cost (WAC) price minus average rebate and 80% patient compliance factor (D). WAC prices as of 2023.[42] Average rebate calculated from the ICER Medications for Obesity Management report.[43] ICER_Obesity_Final_Evidence_Report_and_Meeting_Summary_102022.pdf

* See Prime Therapeutics and MagellanRx July 2023 study.[44]

** Assumed average length of therapy for patients who drop off within 12 months.

*** Assumes non-drop-off patients with obesity are adherent, with PDC scores of 80%.

Utilization and care management impact

A recent study showed that people who stopped taking semaglutide after regular use gained back an average of two-thirds of their prior weight loss.[45] For those patients using a GLP-1 for weight management, long-term GLP-1 adherence, along with lifestyle modification, is critical to achieving and maintaining healthy weight, but patients may not want to continue taking a medication for the rest of their lives. Including education and care management practices, before, during, and after a patient plans to utilize a GLP-1, will provide a higher likelihood of long-term maintained healthy weight.

[41] Dieguez, G., Pyenson, B., Tomicki, S. et al. (March 2021). Obesity in a Claims-Based Analysis of the Commercially Insured Population: Prevalence, Cost, and the Influence of Obesity Services and Anti-Obesity Medication Coverage on Health Expenditures. Milliman Report. Retrieved August 17, 2023, from https://www.novonordiskworks.com/content/dam/nnw/resource-library/pdf/milliman-white-paper.pdf.

[42] WAC prices from information accessed from the Texas Health and Human Services prescription drug price disclosure program. Retrieved August 17, 2023, from https://www.dshs.texas.gov/prescription-drug-price-disclosure-program/data-overview.

[43] Atlas SJ, Kim K, Beinfeld M, Lancaster V, Nhan E, Lien PW, Shah K, Touchette DR, Moradi A, Rind DM, Pearson SD, Beaudoin, FL. Medications for Obesity Management: Effectiveness and Value; Final Evidence Report. Institute for Clinical and Economic Review, October 20, 2022. Retrieved on August 23, 2023, from https://icer.org/assessment/obesity-management-2022/.

[44] Leach, J. et al., op cit.

[45] Wilding, J.P.H. et al., op cit.

Patient concerns about injections, potential treatment side effects (including nausea, vomiting, and diarrhea), or other complications related to GLP-1s may be mitigated by education and support by a medical provider and services. An initial demonstration of the injection process can create a more positive experience for the patient, and education around negative side effects, mitigation strategies, and typical improvement in side effects over time may help patients tolerate the initial discomfort.[46]

Strategies for payers

The booming demand for GLP-1 drugs for weight loss and obesity requires that payers understand all aspects of this class of medications and develop a well-thought-out strategy regardless of whether or not they decide to offer coverage for these products. Below are key actions for payers to help develop such a strategy.

1. **Evaluate coverage of obesity medications.**

   The following are important strategic questions payers can consider when evaluating coverage of obesity medications for weight loss management as part of the overall benefit design.

   - Does the benefit design currently provide coverage for this class?
   - How does coverage for this class align with the organization's broader benefits strategy, such as weight loss surgery?
   - Can a coverage rider buy-up be added (adjustment or add-on to basic policy) for this class?
   - What are the cost implications if the organization decides to cover these medications?
   - If covering this class, are the most cost-effective medications covered, including the impact of formulary rebates?
   - Is there a comprehensive care management plan for patients taking these medications?
   - Are lifestyle modification benefits, such as counseling, diet, and exercise, also covered in conjunction with these medications?
   - Are there medical benefit savings when obesity is reduced by these medications, and can those savings, if any, be quantified?

   The answers to these questions and others are important inputs for payer consideration in developing coverage policies for these drugs.

2. **Ensure appropriate utilization for benefit coverage decisions.**

   These medications are also used to treat diabetes under different brand names which are typically covered (e.g., semaglutide is marketed as Wegovy for the treatment of obesity and Ozempic for the treatment of diabetes). Plan sponsors that do not provide coverage for obesity medications should implement clinical edits or processes to ensure appropriate utilization of the versions indicated for diabetes to control off-label use. Review the plan's utilization management program to see whether diagnosis is confirmed prior to providing coverage for these medications. Consider a "smart prior authorization (PA)," if available, which allows claims to bypass the prior authorization edit when systematically confirming diagnosis with prior medication history or medical diagnosis information. Prior authorization denial rates vary significantly by PBM, therefore a one-size approach does not fit all.

   For obesity coverage, plans should consider prior authorization criteria that follows FDA-approved labeling at a minimum. This will mitigate off-label use by individuals who are not eligible for treatment.

   Whether these medications are covered for obesity or diabetes, payers should consider quantity limits to limit use to the appropriate dose. Plans should also consider verifying the effectiveness of the treatment for each patient with periodic assessments, applying an evaluation for continuation of coverage criteria after a set period.

   Payers should review their plans and PBM edits for compounds to ensure the denial of coverage of compounds with these active ingredients unless and until appropriate compounding criteria are established.

[46] Shomali, M. (January 2014). Optimizing the Care of Patients With Type 2 Diabetes Using Incretin-Based Therapy: Focus on GLP-1 Receptor Agonists. Clin Diabetes. Retrieved August 17, 2023, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4521427/.

Payers should measure and keep track of GLP-1 patient medication adherence and persistency. To encourage medication adherence, consider implementing a financial incentive for patients to participate in an adjunctive lifestyle and nutritional counseling program or in a patient education and wellness program specific for GLP-1s. Patient outcomes should be studied, where costs are compared to attributed savings, if any, from maintained weight loss of patients that are adherent.

3. **Develop a patient engagement strategy to ensure optimal value from this drug class.**

   First-fill medication adherence education and counseling: Prior to taking these medications, patients need to be educated on treatment expectations, administration, side effects, dosing escalation, and management strategies for potential adverse reactions. Throughout therapy, continuous engagement and management of issues as they arise are critical to ensuring patients stay compliant.

   Comprehensive behavioral change support: In addition to counseling on medication, it is critical to provide guidance and support for patients in other areas, including nutrition and diet, physical activity, lifestyle changes, and mental health. This wraparound support is key to achieving and maintaining weight loss.

   Addressing potential socioeconomic inequities: Payers should have a plan in place to remove or minimize potential barriers to treatment for those with social vulnerability challenges. It has been shown that there are racial inequities in the patient populations that receive these treatments, with many of those populations having higher incidence of major adverse cardiovascular events (MACE) that could potentially be reduced with weight loss.[47]

   See Appendix 1 for a comprehensive framework of a patient engagement strategy.

4. **Evaluate the pharmacy supply chain strategy to ensure optimal pricing and value for this category.**

   Payers should ensure that they are receiving optimal value for this drug category, evaluating all available purchase discounts, such as rebates and patient assistance programs. In addition, the formulary rebates eligibility criteria should be considered when implementing the utilization management protocols.

   Payers may consider value-based contracts (VBCs) to help reduce waste and spend. Similar to other classes of drugs where medication persistency is low, a VBC may be designed to reimburse for expenses incurred for patients who do not continue therapy beyond the loading dose. This would require payers, PBMs, and pharmacies to have patient onboarding support programs implemented to enable this agreement.

   Essential aspects that need development to effectively implement value-based agreements include:

   - Reliable and credible total cost of care analytics and modeling capabilities to calculate and forecast return on investment (ROI) for use in the contracting process.
   - Plan designs that maximize value by motivating and incentivizing optimal behaviors when patients enroll in adherence counseling, wellness, nutritional, or other supporting programs.
   - Design agreements that address pain points or potential waste associated with therapy. Other classes such as multiple sclerosis have implemented VBC with low patient adherence and persistency drop-off. These agreements typically provide an incremental discount or additional rebate when agreed-upon measures are not met for an individual patient. They can include some sort of patient support program to help ensure a higher success rate.[48]

[47] Eberly, L.E. ibid.

[48] Kelly, C. (August 8, 2017). Biogen Ventures Into Value-Based Contracts In Multiple Sclerosis. Citeline. Retrieved August 17, 2023, from https://pink.pharmaintelligence.informa.com/PS121212/Biogen-Ventures-Into-Value-Based-Contracts-In-Multiple-Sclerosis.

Conclusion

The GLP-1 agonist class of medications appears to offer a meaningful new opportunity to address obesity in the United States. At the same time, there are several complex clinical, economic, regulatory, and patient engagement considerations that must be addressed in order to maximize value from this class of medications.

Specifically, as the medication adherence and persistency data discussed in this paper confirm, achieving the expected benefits of this therapy will require a robust and strategic level of patient education and counseling support in order to achieve optimal adherence and therapeutic effectiveness of the medications.

In fact, given the high cost of these medications, coupled with existing suboptimal adherence rates, there is high potential for payers and patients alike to experience significant financial waste if medications are not taken exactly as prescribed. This paper provides a thoughtful care management framework with robust medication counseling and education, which are both considered essential for payers and relevant healthcare stakeholders if they choose to offer coverage for these medications.

Methods

The values presented in Figure 2 were developed by Milliman using the Milliman MedInsight® Emerging Experience research data set, which is a database of nationwide de-identified healthcare claims data for over 70 million unique individuals with dates of service spanning 2017 to the current year. Approximately 75 healthcare organizations contribute monthly data to this research database, which is currently refreshed quarterly. The database provides a comprehensive view of services received by patients provided by any healthcare professional in any location or setting billed to insurance, including approximately 1.7 million medical professionals and 340,000 healthcare facilities. The study population included individuals enrolled from January 1, 2022, through February 28, 2023. Sources of coverage were categorized as commercial—health maintenance organization (HMO), preferred provider organization (PPO), ACA, and other—with upwards of 37 million; Medicare Part D stand-alone prescription drug plan, with upwards of 2 million; Medicare Advantage Part D prescription drug plan, with more than 2 million; and Medicaid (HMO, PPO, other) with more than 8 million enrollees.

National Drug Codes (NDC) for GLP-1s included Wegovy, Ozempic, Saxenda, Victoza, and Mounjaro. Findings were not risk- or acuity-adjusted.

Caveats, limitations, and qualifications

We summarize administrative claims data, reflecting healthcare services paid by insurers. Our results do not capture claims that were denied or cash-paid by patients outside of insurer-paid healthcare encounters or events. The summarized data have not been geographically or demographically adjusted and reflect the observed populations and geographies represented in the Milliman MedInsight® Emerging Experience research data set.

The material in this report represents the opinion of the authors and is not representative of the view of Milliman. As such, Milliman is not advocating for, or endorsing, any specific views contained in this report related to GLP-1 medications.

The information in this report is designed to provide an overview of the GLP-1s for weight loss for payers. This information may not be appropriate, and should not be used, for other purposes. We do not intend this information to benefit any third party that receives this work product. Any third-party recipient of this report that desires professional guidance should not rely upon Milliman's work product but should engage qualified professionals for advice appropriate to its specific needs.

The American Academy of Actuaries requires its members to identify their credentials in their work product. Deana Bell and Peter Heinen are consulting actuaries of Milliman, are members of the American Academy of Actuaries, and meet the qualification standards of the Academy to render the actuarial opinion contained herein. To the best of their knowledge and belief, this report is complete and accurate and has been prepared in accordance with generally recognized and accepted actuarial principles and practices.

Acknowledgments

The authors gratefully acknowledge Michael Hadfield and Dale Skinner from the Milliman MedInsight team for their invaluable contribution in analyzing the Milliman MedInsight® Emerging Experience research data set.

Appendix A: Framework for a GLP-1 patient engagement and adjunctive lifestyle and nutritional counseling strategy

CARE MANAGEMENT COMPONENT	DEFINITION	TOOLS AND STRATEGIES
Stratification	Identify, segment, and prioritize, patient populations at highest risk who offer the greatest potential for improvements in health outcomes	– Health risk assessments/surveys – Predictive models to identify high-risk opportunities for care management – Case finding (e.g., chart reviews, surveys) – Referrals (from member, provider, community) – Integrate health equity/social determinants of health considerations in all segmentation and prioritization activities
Analytics	Utilize analytics capabilities to identify specific clinical opportunities and provide the intervention opportunities to appropriate healthcare professionals to execute engagement strategies	– Ensure all analytics methodologies adhere to evidence-based guidelines – Integrate opportunities using technology where possible – Generate action-oriented intervention opportunities that are intuitive to the audience
Intervention	Directly engage all relevant healthcare stakeholders, including the patient, provider, pharmacist, PBM, and payer, to maximize clinical outcomes and reduce costs	– Create a comprehensive patient educational program around overall healthy habits, weight loss strategies, medication dosing, and side effects management – Develop an infrastructure and processes to engage with each healthcare stakeholder – Provide regular cadence consultation and counseling based on the individualized needs of the patient – Implement motivational interviewing techniques
Measurement	Collaborate with all healthcare stakeholders to ensure that quality and savings metrics are relevant to each and useful for ongoing strategic decision-making	– Leverage population management and care management applications to track all relevant key performance indicators (KPIs) and measures – Conduct periodic assessments of therapeutic impact and progress for each patient and take action as appropriate – Utilize newer, more sophisticated predictive modeling techniques to estimate reductions in total cost of care (if any) and other potential cost savings related to healthier patients – Identify opportunities for value-based care and outcomes-based contracting

Milliman

Milliman is among the world's largest providers of actuarial, risk management, and technology solutions. Our consulting and advanced analytics capabilities encompass healthcare, property & casualty insurance, life insurance and financial services, and employee benefits. Founded in 1947, Milliman is an independent firm with offices in major cities around the globe.

milliman.com

CONTACT

AJ Ally
aj.ally@milliman.com

Deana Bell
deana.bell@milliman.com

Melody Craff
melody.craff@milliman.com

Jeffrey Garbe
jeffrey.garbe@milliman.com

Mark Gruenhaupt
mark.gruenhaupt@milliman.com

Peter Heinen
peter.heinen@milliman.com

Ellyn Russo
ellyn.russo@milliman.com

REQUEST FOR INFORMATION NUMBER:270-20240419GLP
ADDENDUM NUMBER:1

REQUEST FOR INFORMATION (RFI) ADDENDUM

Issuing Agency:	North Carolina State Health Plan for Teachers and State Employees
RFI Number:	270-20240419GLP
RFI Description:	GLP-1 Solutions
RFI Opening Date and Time:	May 31, 2024, 2:00 PM ET
Addendum Number:	1
Addendum Date:	May 6, 2024
Purchasing Agent:	Kimberly Alston

FAILURE TO RETURN THIS ENTIRE ADDENDUM MAY SUBJECT YOUR RESPONSE TO REJECTION.

1. Addendum Number 1 is in response to questions submitted. Responses to questions begin on the next page.
2. Return one signed copy of this Addendum with your RFI response.

****

Execute Addendum Number 1, RFI Number 270-20240419GLP:

Respondent: AmVentureX, Inc, dba Biocoach

Authorized Signature: [signature]

Name and Title (Print): Michael Silverstein

Chief Product officer

Date: May 29, 2024

Question #	Document Section	Respondent Question	State's Response
1	General	Since [Our Business] and the procedure of endoscopic sleeve gastroplasty (ESG) isn't a GLP-1 or manufacturer, what is your suggestion for us re: the RFI? We believe that ESG would be an excellent option for the NCSHP to consider.	Pursuant to RFI Section 3.0 C. 2. "Multiple Responses," the Plan requests that you submit any information, potential solutions, or alternatives relevant to the matter of weight loss benefits/solutions, for the Plan's review and consideration as a response to the RFI.
2	General	What is the timeline for a potential decision? What is the desired go-live date?	This is a request for information only, and not a request for services. There is not a set timeline for any decisions. In the Plan's sole discretion, the Plan may take any feasible and financially sound steps to address the fiscal issues of coverage for GLP-1 and GIP-GLP-1 agonists for weight loss, including other potential weight loss alternatives for Plan members.
3	General	Who is North Carolina State Health Plan for Teachers and State Employees pharmacy benefit manager? Is RX carved in or out of the health plan?	The Plan's Pharmacy Benefit Manager (PBM) is CVS Caremark. Pharmacy is carved out from the medical benefit. The Plan's current third-party administrator is Blue Cross Blue Shield of North Carolina.
4	Section 1.0, Page 2	Is there a current vendor providing these services? If so, how may I obtain copies of any incumbent contract documents?	The Plan discontinued coverage for GLP-1s, GIP-GLP-1 agonists, and other similar new molecular entities, for the purpose of weight loss effective April 1, 2024. These benefits were provided through the Plan's PBM Contract. No current vendor provides services that includes these molecular entities as a covered benefit for weight loss. The Plan follows the provisions of the North Carolina Public Records Act for public documents with requests submitted to PublicRecords@nctreasurer.com.
5	Section 2.0, Page 2	Who/what type of physician was prescribing the majority weight loss drugs?	There were no limitations on the type of provider with prescribing authority that can prescribe these medications. That is true for all medications. The requirement is only that the member have a valid prescription and meet the utilization management requirements (if applicable).
6	Section 2.0, Page 2	If this RFI greenlights a solicitation, what is the estimated time frame for procurement?	This is a request for information only, and not a request for services. There is not a set timeline for any decisions. In the Plan's sole discretion, the Plan may take any feasible and financially sound steps to address the fiscal issues of coverage for GLP-1 and GIP-GLP-1 agonists for weight loss, including other potential weight loss alternatives for Plan members.

Question #	Document Section	Respondent Question	State's Response
7	Section 2.0, Page 2	What is the anticipated contract value?	This is a request for information only, and not a request for services. We do not have an anticipated contract value at this time.
8	Section 2.0, Page 2	What is the number of patients who were taking GLP-1 and GIPs for weight loss in 2023? What is the estimated growth year over year? Goals for the program for the next 5 years?	There were approximately 24,750 utilizers in calendar year 2023. The estimated growth year over year is 51.2% in 2024; 28.6% in 2025 and 14.8% in 2026. The Plan's goal is to have a solution in place that permits benefit coverage for Plan Members in a financially sustainable manner.
9	Section 2.0 B.1., Page 2	B. Establish a pricing framework that would permit the Plan to provide such benefit coverage in a fiscally responsible manner in order to maintain financial sustainability. For example, the Plan seeks the ability to: 1. Pay for varying percentages of the unit cost according to medical necessity considerations. Can you please elaborate on what this is referring to (i.e., GLP-1)?	Under this cost model, the member's cost share for the medication would vary based on need. For example, a member with a lower BMI and no chronic conditions would have a higher cost share than someone with a BMI of 40 and multiple comorbidities.
10	Section 2.0 B., Page 2	Is there a list of medications that ideally would be included for weight loss? Will the state consider "off-label" prescriptions i.e., Ozempic for weight loss instead of Wegovy or Moujaro instead of Zepbound? Is the state open to alternative options such as sterile compounding for these medications while they're on the FDA shortage list?	The specific brand names may expand over time but currently include Saxenda, Wegovy, and Zepbound. The Plan is aware of the possibility for off label use by prescribers and have put specific utilization management guidelines in place to avoid this. The Plan is not interested in off labeled use of a GLP-1, GIP-GLP-1 agonist FDA approved for diabetes (Ozempic, Mounjaro, etc) within our current PBM framework. Consequently, any off labeled use would have to be fully separate from the existing pharmacy benefit administrative processes. The Plan is open to reviewing all legal, feasible, and fiscally sound solutions. Any solution would have to be structured such that it would be administratively feasible.

Question #	Document Section	Respondent Question	State's Response
11	Section 2.0 C., Page 2	What were the specific parameters for coverage for GLP-1 and GIPs for weight loss before they were removed from the plan? Is there any data from when the meds were covered on efficacy of certain programs or requirements?	The Plan was using the standard utilization management guidelines for the GLP-1 and GIP-GLP-1s for weight loss provided by our PBM (CVS Caremark). This included a prior authorization in line with FDA approved BMI criteria, participation in a comprehensive weight management program for at least 6 months prior to using drug therapy, and quantity limits. Prior to 1/1/2024 this prior authorization permitted attestation from providers and did not require documentation. CVS Caremark updated the standard UM beginning 1/1/2024. This update requires documentation of BMI and comorbid conditions (if applicable). However, the update does not require documentation for participation in a weight management program - CVS permits an attestation. Grandfathered members eligible after 1/1/2024 that had prior authorizations due between 1/1/2024-4/1/2024 were subject to these new guidelines.
12	Section 2.0 C.1., Pages 2 and 3	Would group sessions, virtual coaching or webinar format be allowable for lifestyle coaching options? Will you allow any health coaches who are not certified NBC-HW? (National board-certified health wellness)	Pursuant to RFI Section 3.0 C. 2. "Multiple Responses," the Plan is open to reviewing all alternatives and potential solutions.
13	Section 2.0 C.4., Page 3	Please explain the prohibition on BMI measurements via telehealth. Given the rural nature of North Carolina, in person measurement requirement is likely a very large barrier to care.	The Plan begins within a frame of reference that a provider should meet with the patient to assess BMI and clinical necessity. However, solutions that meet the objective of ensuring an accurate and medically appropriate diagnosis and include components to subsequently ensure correct measurements that maintain accountability for continuation of therapy would be welcomed.
14	Section 2.0 D.1., Page 3	Is a waist to height or waist to hip ratio acceptable in lieu of BMI for program qualification?	The Plan prefers to use BMI for program qualifications if for no other reason than it is used by the FDA for indication, but the Plan would be open to multiple measures that represent alternative thinking.

Question #	Document Section	Respondent Question	State's Response
15	Section 2.0 D.3., Page 3	Are there any specific qualifications or components required for the weight loss lifestyle management?	There are on specific requirements, but documentation of participation and completion will be required. Attestations will not be sufficient.
16	Section 2.0 E., Page 3	What are the determinants of the program decision in terms of weighted value? -Price -Patient experience -Overall value -Small business/Local NC business	There are no set determinants for making program decisions at this time. The Plan will review all submissions for feasibility and achieving the Plan's fiscal goals solutions.