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Memorandum

To: **North Carolina State Health Plan**

From: Eileen Pincay, R.Ph., Vice President, National Pharmacy Practice Leader

Date: August 28, 2023

Re: Review of GLP-1 Medications and Management Opportunities

The North Carolina State Health Plan (SHP) has seen a material spike in pharmacy spend as a result of the newer Anti-Obesity Medications (AOMs), specifically Saxenda and Wegovy. The cost has risen under the SHP from approximately $3 million per month, two years ago, to over $14 million per month in 2023. There are approximately 20,000 plan members currently using these medications. Continuing to cover these medications with existing procedures costs the plan $168 million dollars a year in prescription drug costs, with minimal savings on medical costs. We would expect these costs to continue to increase and could exceed $300 million annually within the next 5 years. Note that these medications are receiving rebates of approximately [redacted]%, reducing the net costs to the plan. CVS confirmed the claims data reported and highlighted in this memo was before rebates, meaning the net costs are less.

Based on these previously unanticipated cost increases, there is interest in evaluating different options to help manage AOM costs. Segal's National Pharmacy Benefit Practice requested data from SHP's PBM, CVS Caremark (CVS), representing utilization, cost information and utilization management program offerings around the glucagon like peptide medications or GLP-1s for both obesity and diabetes. This memo incorporates Segal's clinical review of CVS's prior authorization programs, as well as observations and thoughts on applying prior authorization for these drugs.

Segal's pharmacy consultants evaluated the effectiveness of the current Rx program design versus industry norms, pharmacy trends and clinical best practices on weight loss management and diabetes. We highlighted current plan strengths and weaknesses and identified opportunities for possible modifications. Some data and analysis we included in this memo:

- Background research on GLP-1 medications in diabetes and obesity.
- Data received from SHP's current PBM vendor (CVS) and, if available, other industry peers.
- SHP's program design and utilization information from CVS, ensuring that recommendations are specific and actionable.
- A comprehensive review of CVS's current clinical and cost containment programs around diabetes and obesity, which is inventoried and reported.
- Our clinical review also includes commentary as well as recommendations on the Rx program, which may include potential program opportunities to better control cost and utilization.
- Information on what other states and/or plans are doing in regards to AOM coverage, if available, and AOM management, if any, which may spark other ideas for cost control.

Redactions provided by CVS Caremark at the request of Novo Nordisk

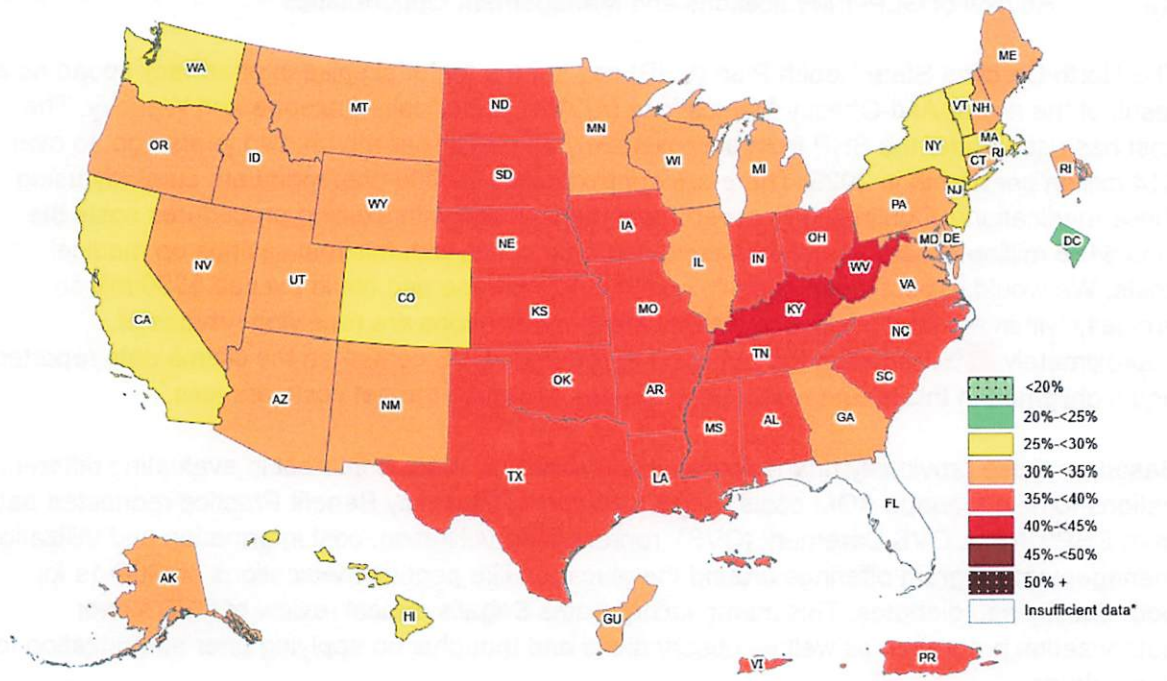
Obesity and GLP-1 Medications

Background

It is currently estimated that 97 million adults are overweight or obese in this country and the prevalence of obesity varies by state, with the South having the highest prevalence of obesity, followed by the Midwest states.[1] (See Figure 1.) There are also a number of medical issues related to obesity such as type 2 diabetes, coronary heart disease, hypertension and certain cancers. Additionally, there is a push now to cover obesity as a chronic disease rather than a lifestyle disease. North Carolina ranks 15th in states impacted by obesity.[2]

Figure 1

Prevalence of Obesity Among U.S. Adults by State and Territory, 2021 (source CDC)



The large percentage of the overweight or obese population in the US, which continues to grow each year, has led to obesity now being considered a "chronic disease." With the release of the popular GLP-1 receptor agonist drug Wegovy in 2021, specifically used for weight loss, it is possible that there may be a major push by pharma to make AOM coverage a requirement or even an essential benefit. This will require new studies that show effectiveness of the drugs and offsetting long-term costs to justify the price. To date, there are no studies that show a positive ROI for these costly drugs.

Obesity advocacy organizations have also been pressuring Congress to pass the *Treat and Reduce Obesity Act*, which would include expanding anti-obesity drug coverage for Medicare recipients.[3] Our clients are actively evaluating the cost versus the benefit of covering anti-obesity medications (AOMs), as obesity is linked with heart disease, stroke, Type II diabetes, and certain types of cancer. Prevention of these illnesses appears to be key, both in terms of

[1] Cdc.gov
[2] obesityactioncoalition.org
[3] https://thehill.com/policy/healthcare/4148133-inside-the-push-to-get-weight-loss-treatment-covered-by-medicare/

long-term health outcomes for plan participants, as well as costs. Given the cost of these drugs and the obesity epidemic in our country, it is not an easy decision for our clients.

Although AOMs have been on the market for many years, serious safety concerns with some of the older AOMs prompted the FDA to set guidelines that restricted their use to only a small percentage of adults. Some of these older AOM drugs were also pulled from the market due to their life-threatening side effects. In the late 1990's, the FDA recommended that new drugs to treat obesity undergo longer testing prior to approval. For these reasons, newer drugs either combined medications with good safety records individually or those that have been used for many years to manage Type II diabetes before are now being used as obesity treatments.

Drugs in the newest class, the GLP-1s, were first FDA approved to treat Type II diabetes in 2005 and were found to have the added benefit of causing weight loss (by appetite suppression from delayed gastric emptying). One of the newer GLP-1 drugs, semaglutide, (marketed as Ozempic for diabetes and Wegovy for weight loss) showed a 12.4% average weight loss in a study published in 2021. With the tremendous amount of Pharma advertising and exposure on social media, there was a significant and unforeseen increase in utilization, which led to widespread shortages and increased costs to health plans, including SHP.

Wegovy is extremely expensive and has a cash discount price of approximately $1,349 for a month's supply.[4] A year's worth could potentially be more than $15K, which is over double the Institute for Clinical & Economic Review (ICER)'s pricing recommendation, making Wegovy at its current pricing not cost-effective.[5] In comparison, Ozempic, with the same active ingredient as Wegovy, marketed for Type 2 diabetes, has a cash discount price of approximately $930.[6] Although the manufacturer has indicated that Wegovy has more of the active ingredient, some still argue that charging people more for obesity is not equitable. Due to Ozempic's lower cost compared to Wegovy, Segal is aware of at least one PBM who began to allow Ozempic coverage for weight loss; however, negative rebate impact forced them to update their policy to not allow this.

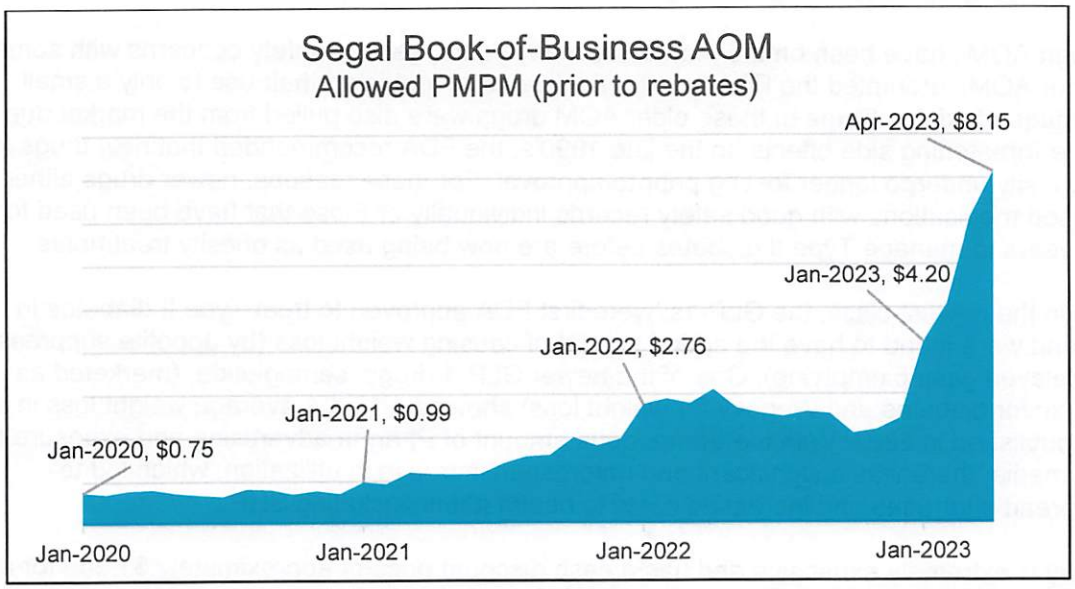
Utilization and Cost

This section reviews the trends in the GLP-1 medication utilization for obesity as well as current concerns seen with utilization of some of these newer GLP-1 diabetic agents. One concern that many have is that while these GLP-1 drugs can be successful, the weight regain after stopping treatment is common. With this in mind, these drugs are sometimes considered lifetime drugs. This, in turn, may mean longer use for these medications with continued high costs that may not be sustainable and not provide a long-term savings like other high cost drugs that cure the disease (e.g., Hepatitis C drugs).

With the increased use of of GLP-1s, plan sponsors that cover AOMs have seen a dramatic increase in spending on these drugs in recent years. In 2018, the average cost for Segal clients who cover AOMs was $0.50 per member per month (PMPM) looking across all AOMs - GLP-1s and older or non-GLP-1 AOMs. By 2022, that cost had more than quadrupled to $2.76 PMPM.[7] Continuing in 2023, the average PMPM cost has almost tripled to $8.15 PMPM, based on four months of data. We expect this trend to continue. See Figure 2 on the following page.

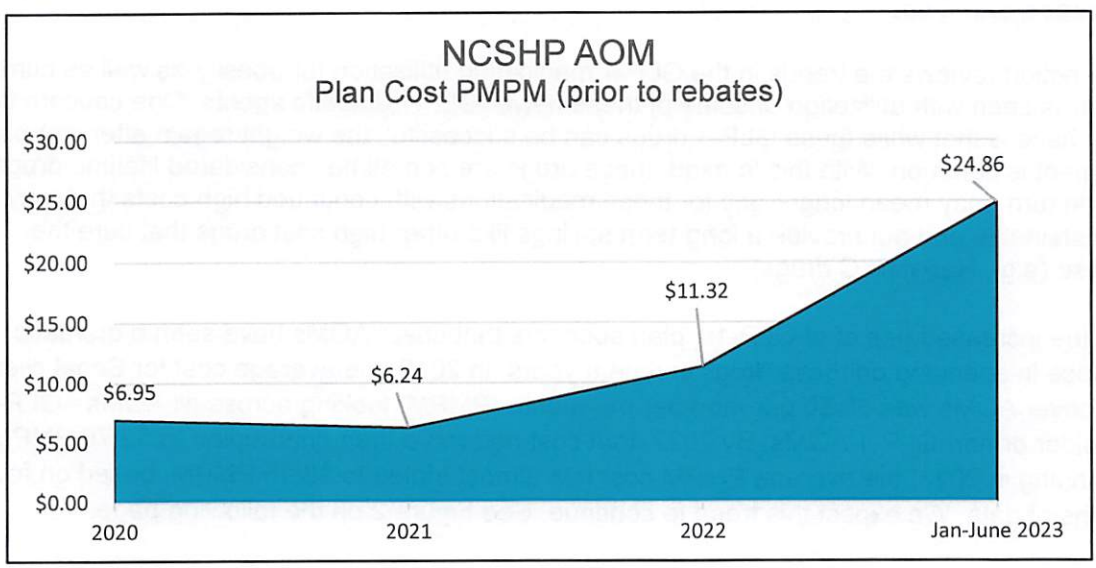
[4] https://www. bihealthcare.com/wegovy-cost
[5] https://icer.org/assessment/obesity-management-2022
[6] https://www.goodrx.com/ozempic
[7] Eileen Pincay, January 23, 2023, *New Drugs for Weight Loss: What Plan Sponsors Need to Know*, Segal, accessed March 2023 <https://www.segalco.com/consulting-insights/new-drugs-for-weight-loss-what-plan-sponsors-need-to-know>

Figure 2



In reviewing SHP specific data on AOM costs (includes all GLP-1s and the older AOMs), SHP costs are significantly higher than what we are seeing in Segal's book-of-business. This is likely aided by a very low member cost share in SHP's program, making these expensive drugs affordable to members. For SHP in 2020, net costs (prior to rebates) were $6.49 PMPM and in 2022 net costs increased 1.6 times to $11.32 PMPM. For the first six (6) months of 2023, the net costs are $24.86 PMPM, which is 3.6 times more than 2020. See Figure 3.

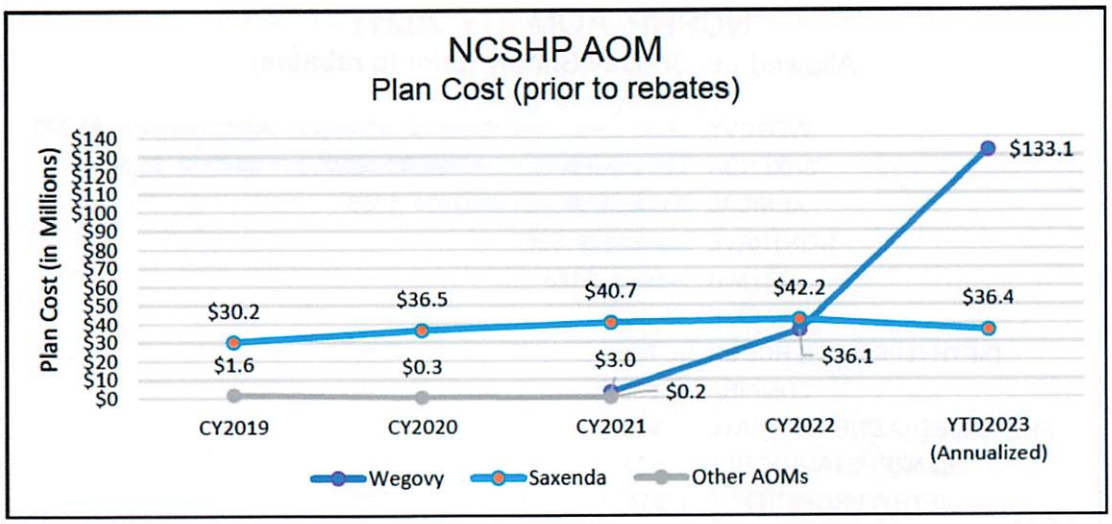
Figure 3



In addition, when comparing the net plan costs (prior to rebates) for SHP across all the different AOMs, Saxenda steadily increased from 2019 to 2022 (about $30.2M to $42.2M) and made up more than 90% of the market share costs. Wegovy launched in 2021 and caught up to Saxenda

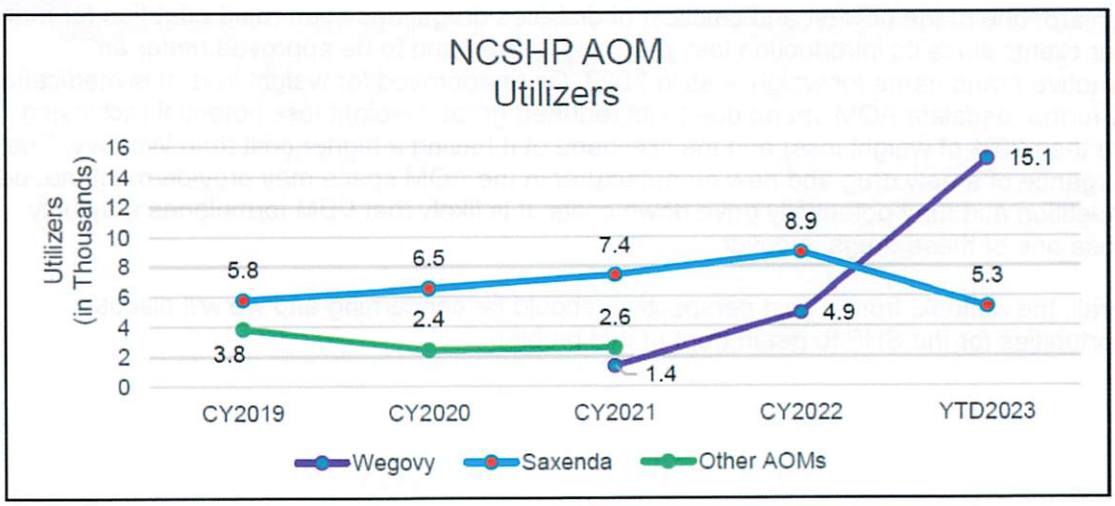
in 2022 and both had comparable market share costs (about $36.1M and $42.2M, respectively). Wegovy more than tripled SHP costs in 2023 YTD at about $66.6M and made up more than 75% of market share costs. Note that 2023 is only for 6 months and, for comparison purposes in Figure 4, we have assumed annual costs will be twice these amounts; however, we note it is likely they will be more than the double we have assumed. From 2020 and 2021, the older AOMs represented less than 1 percent (about $251K in 2020 and about $154K in 2021) of AOM costs.[8] See Figure 4.

Figure 4



In regards to utilization, in 2019 and 2020, Saxenda made up 60% and 73% of utilization, respectively (or 5,783 and 6,532 utilizers, respectively). The older AOMs made up the rest. In 2021, Saxenda still dominated at about 65% of the market share, while Wegovy made up only 12%. In 2022, Wegovy utilizers grew significantly and in 2023 YTD, Wegovy utilizers (15,091) make up most of the market share.[9] See Figure 5.

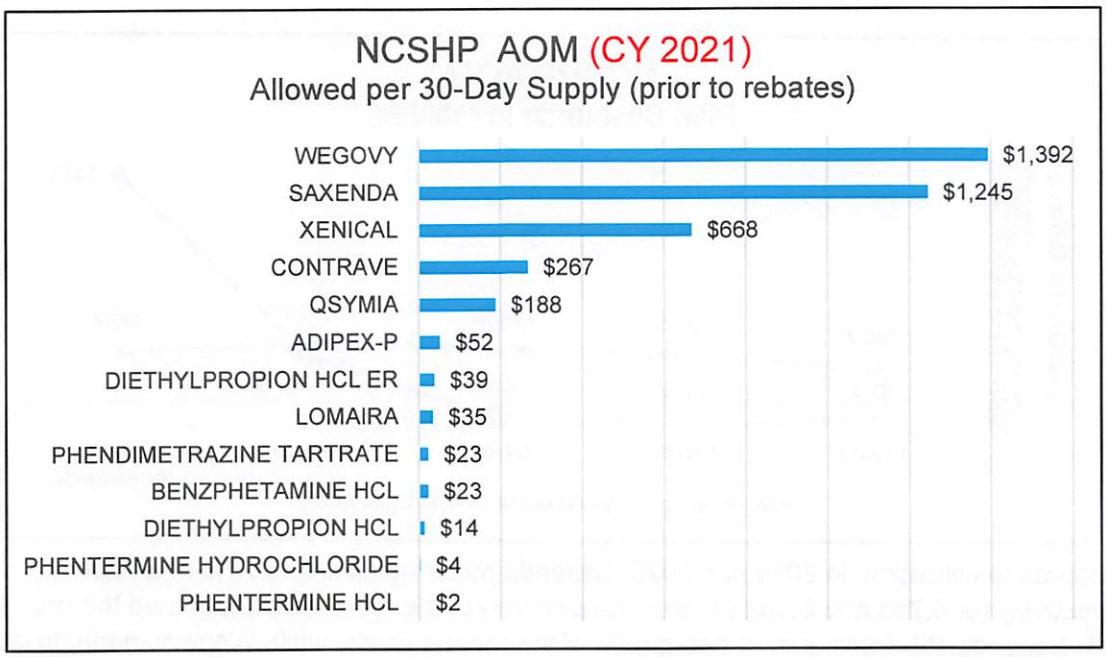
Figure 5



[8] Segal was unable to attain 2022 and 2023 SHP data for the non-GLP-1 AOMs
[9] Segal was unable to attain 2022 and 2023 SHP data for the non-GLP-1 AOMs

Below is the average allowed cost per 30-day supply for AOMs filled by SHP members during calendar year 2021. Wegovy had the highest allowed cost at $1,392 per 30-day supply followed by Saxenda at $1,245. The other non-GLP-1 AOMs are much cheaper with allowed cost ranging from $2 to $668 for a 30-day supply. Xenical had the highest cost amongst the non-GLP-1 AOMs followed by Contrave. Note that these figures do not reflect rebates. See Figure 6.

Figure 6



CVS indicated the Wegovy and Saxenda receive about [redacted]% in rebates, lower the cost to $[redacted] and $[redacted] respectively.

Mounjaro, one of the newest and costliest of diabetes drugs, has seen rapid adoption for many of our clients since its introduction last year, and is expected to be approved under an alternative brand name for weight loss in 2023. Once approved for weight loss, this medication may further escalate AOM spend due to its reported greater weight loss potential (achieving more than 20% of weight loss) and the likelihood of it having a higher cost than Wegovy. The emergence of a new drug and new manufacturer in the AOM space may provide much needed competition and may potentially drive down costs. It is likely that PBM formularies may only choose one of these drugs to cover.

Overall, the outlook, from a cost perspective, should be concerning and we will discuss opportunities for the SHP to get in front of this problem.

Review of Prior Authorizations for Wegovy and Saxenda

It is our understanding that CVS currently offers the following Prior Authorizations to help manage AOMs:

- PA on GLP-1s – *Wegovy and Saxenda*
- PA on all other AOMs (non-GLP-1 medications) – *Contrave, Qsymia, Xenical, benzphetamine products, diethylpropion products, phendimetrazine products, phentermine products, etc.*

How the PA works: All Wegovy and Saxenda claims will reject with a PA. Criteria depends on whether the request is initial or a continuation of therapy and whether it is an adult or pediatric patient. Additionally, criteria for baseline weight loss, comprehensive weight management, BMI values according to FDA labeling (BMI values differ for pediatrics), use with a reduced calorie diet and increased physical activity are all considered, as well as stable maintenance dosing.

Segal has reviewed the standard CVS prior authorization criteria for both Wegovy and Saxenda and find that both policies meet FDA and clinical guidelines. CVS confirmed that there is no negative rebate impact from implementing this edit.

SHP has had the CVS standard prior authorization in place to manage the AOMs since their inception of AOM coverage. CVS has self-reported that the annualized net savings from this program was about $22.8M in 2022 and $15.9M in 2023 (January to June 2023). These numbers are typically somewhat overstated, but the program appears to offer some protection for clients.

Review of Prior Authorization for Older AOMs

Although the older AOMs have lower drug costs (average net cost $7.87 per script in 2022), prior authorizations may also make sense to implement across all AOMs (including the older AOMs) as this is following FDA and clinical guidelines and will ensure appropriate use.

Segal has reviewed the criteria for the other AOMs and find that the policies meet FDA and clinical guidelines. Like the newer AOMs, there is no rebate impact to implement this edit.

Other ideas if SHP wants to consider stricter coverage for AOMs:

Given the growth of the AOMs and their potential for abuse, we believe it is prudent to work with CVS to customize your specific PAs, assuming SHP is open to stricter coverage and still prefers to cover AOMs. On the next couple of pages, we provide some custom PA opportunities. Note that these additional criteria will still need to be vetted through SHP P&T (including attorney general's office to ensure compliance with all applicable rules and regulations) and CVS, as this will be considered "custom criteria" and may or may not have rebate impact. Even with the large rebates, the costs are extremely high. Each opportunity will need to consider the potential additional per claim cost with the offset of the lower utilization.

Of course there is still the option for SHP to not cover or exclude the higher cost AOMs, such as Wegovy, Saxenda and Mounjaro.

Customized Prior Authorization Opportunities for Adults and Pediatrics	Segal Comments
For adult patients who are continuing therapy with Wegovy or Saxenda Patient needs to meet **one of the following**: – At baseline (prior to the initiation of Wegovy or Saxenda), patient had a BMI ≥ 30 kg/m2; **OR** – At baseline (prior to the initiation of Wegovy or Saxenda), patient had a BMI ≥ 27 kg/m2 and at least one of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, or cardiovascular disease; **AND** Wegovy/ Saxenda will be used concomitantly with behavioral modification and a reduced-calorie diet	CVS has separate policy criteria for initial and continuation therapy for both Wegovy and Saxenda. Segal found that the **initial therapy** criteria for adults was acceptable. For continuation therapy criteria, if customization is allowed by CVS, and SHP is open to stricter coverage, then Segal recommends adding additional criteria to the existing Saxenda and Wegovy policies for "continuing therapy criteria for adults." *Segal finds that the added suggestions still fall within clinical guidelines and will likely not have a negative rebate impact.*
For pediatric patients (12 and older) who are continuing therapy with Wegovy or Saxenda Patient needs to be at a baseline (prior to initiation of Wegovy or Saxenda), patient had a BMI >=95th percentile for age and sex **AND** Wegovy/ Saxenda will be used concomitantly with behavioral modification and a reduced-calorie diet **AND** for Wegovy, patient has had a reduction in BMI of ≥ 1% from baseline (prior to the initiation of Wegovy) – Note that current CVS Caremark criteria does not put a percentage and just states that patient has a reduction from baseline BMI for Wegovy but for Saxenda it does have the 1%.	CVS has separate policy criteria for initial and continuation therapy for both Wegovy and Saxenda. Segal found that the **initial therapy** criteria for pediatrics was acceptable. If customization is allowed by CVS, and SHP is open to stricter coverage, then Segal recommends adding additional criteria to the existing Saxenda and Wegovy policies for "continuing therapy criteria for pediatrics." *Segal finds that the added suggestions still fall within clinical guidelines and will likely not have a negative rebate impact.*

<table>
<tr>
<td>For adult patients - for both Wegovy and Saxenda PA initial criteria - Increasing BMI thresholds for approval to Class II obesity (BMI 35 or higher) or 30 or higher with comorbidities and do not recommend for use in overweight (BMI 27 or higher) with comorbidities at this time.</td>
<td>This is stricter than FDA approved indications, and is intended solely for cost management purposes (versus not covering at all). Segal notes that Victoza goes off patent this year and perhaps its generic could be the first line GLP-1 for those overweight who do not need higher weight loss (as seen with the newer GLP-1s).

Due to concerns for excessive cost, some plans may be considering implementing stricter coverage polices with example criteria to left especially for those plans who do not cover anti-obesity medications currently.

This will most likely have rebate impact.</td>
</tr>
<tr>
<td>For pediatric patients - Not cover AOMs for children even though Wegovy and Saxenda are FDA approved for children 12 to 17 years.</td>
<td>This idea is based on the fact that the trials that FDA based approval on enrolled only 251 children (Saxenda) and 201 children (Wegovy) and most likely will have rebate impact.

Segal can expand on these thoughts if interested in this discussion.

For SHP, Segal requested the number of pediatric patients on AOM medications:

<table>
<tr><th>Claim Fill Year</th><th>Product/Drug Name</th><th>Total Net Cost</th><th>Total Utilizers</th></tr>
<tr><td>2022</td><td>QSYMIA</td><td>$1,213.49</td><td>5</td></tr>
<tr><td>2023</td><td>QSYMIA</td><td>$985.80</td><td>3</td></tr>
<tr><td>2020</td><td>CONTRAVE</td><td>$[redacted]</td><td>1</td></tr>
<tr><td>2022</td><td>LOMAIRA</td><td>$[redacted]</td><td>2</td></tr>
<tr><td>2020</td><td>PHENTERMINE HYDROCHLORIDE</td><td>$8.76</td><td>2</td></tr>
<tr><td>2021</td><td>PHENTERMINE HYDROCHLORIDE</td><td>$[redacted]</td><td>11</td></tr>
<tr><td>2022</td><td>PHENTERMINE HYDROCHLORIDE</td><td>$2.29</td><td>11</td></tr>
<tr><td>2023</td><td>PHENTERMINE HYDROCHLORIDE</td><td>$[redacted]</td><td>1</td></tr>
<tr><td>2021</td><td>SAXENDA</td><td>$64,334.61</td><td>18</td></tr>
<tr><td>2022</td><td>SAXENDA</td><td>$130,611.73</td><td>39</td></tr>
<tr><td>2023</td><td>SAXENDA</td><td>$42,103.69</td><td>15</td></tr>
<tr><td>2022</td><td>WEGOVY</td><td>$12,372.48</td><td>5</td></tr>
<tr><td>2023</td><td>WEGOVY</td><td>$181,853.65</td><td>50</td></tr>
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<tr>
<td>Prefer the older AOMs as a step before approving GLP-1s in overweight patients (BMI 27 or higher with cardiovascular risk factors).</td>
<td>This is intended for cost management purposes (versus not covering at all).

Due to concerns for excessive cost, some plans may be considering implementing stricter coverage polices with example criteria to left especially for those plans who do not cover anti-obesity medications currently.

This will most likely have rebate impact.</td>
</tr>
</table>

Redactions provided by CVS Caremark at the request of Novo Nordisk

Diabetes and GLP-1 Medications

Background

For purpose of the GLP-1 discussion, we will also dive into the diabetes condition. Over 37 million people in the United States have diabetes and 96 million people aged 18 years or older have prediabetes.[10] Approximately 1,014,358 people in North Carolina, or 12.4% of the adult population, have diagnosed diabetes and about 35% who have prediabetes.[11]

Diabetes medications account for a large proportion of plan spend and high trend in this category is not unique to SHP. The main medication therapeutic class driving higher spend are the glucagon-like peptide-1 receptor agonists (GLP-1s).

GLP-1 medications have been utilized ever-increasingly in recent years after medical guidelines have made them preferred medications in some diabetic patients, with weight loss being a key element to reversing diabetes. Both Victoza and Ozempic are FDA-approved for weight loss under the alternative brand names Saxenda and Wegovy, respectively. The primary difference being the dosage amount of the active ingredient.

Utilization and Cost

This section reviews the trends in the GLP-1 medication utilization for diabetes as well as current concerns seen with utilization of some of these newer GLP-1 diabetic agents.

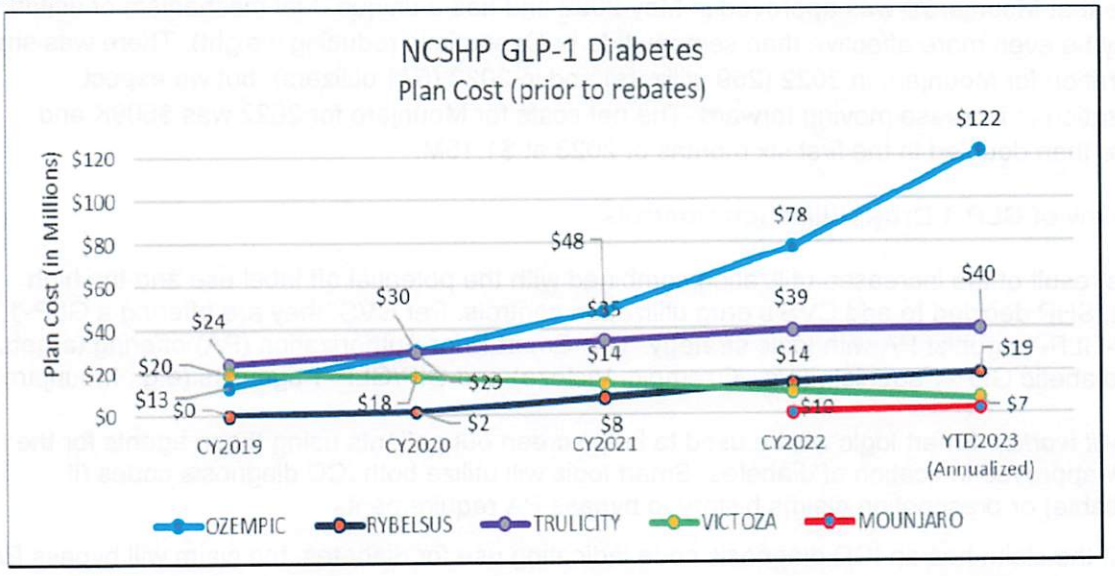
Under the new diabetes guidelines issued in 2021, the American Diabetes Association also recommends that healthcare professionals consider prescribing GLP-1 agonists or SGLT-2 inhibitors (another class of medications that treat diabetes, such as Jardiance®) to reduce health complications, regardless of someone's A1C level or metformin use. These medications may reduce risk of cardiovascular mortality in type 2 diabetics with established cardiovascular disease or who are at high risk of cardiovascular disease. The standards of diabetes care continue to be reviewed and updated each year. In the 2023 guidelines, the ADA emphasizes supporting higher glucose control, weight loss and focusing on obesity as a chronic disease.[12]

In light of the new diabetes guidelines and social media buzz, it is not surprising that we are seeing increased utilization of GLP-1s. In fact, over the past several years, the percentage of plan spending on GLP-1 medications has increased faster than other diabetic medications.[13] For SHP, since 2021, plan spending on GLP-1 medications has nearly doubled, with the drug Ozempic leading the growth. Ozempic continues to have the highest plan spend versus the other GLP-1/ GLP-1 diabetic medications, $48M in 2021, $78M in 2022, and projected to be nearly $130M in 2023. Trulicity had the second highest plan spend for 2021 and 2022 (about $35M and over $39M, respectively). Its cost has somewhat leveled out, projecting to be $40M in 2023, with newer drugs picking up the increased costs. Rybelsus (which is the first oral GLP-1 medication) also had some increases in spend as well, growing from $2M in 2020, to nearly $20M in 2023. In total, these drugs continue to have massive cost increases, they are

[10] CDC.gov
[11] ADA, The Burden of Diabetes in North Carolina
[12] Eileen Pincay, January 23, 2023, *New Drugs for Weight Loss: What Plan Sponsors Need to Know*, Segal, accessed March 2023 <https://www.segalco.com/consulting-insights/new-drugs-for-weight-loss-what-plan-sponsors-need-to-know>
[13] Eileen Pincay, January 23, 2023, *New Drugs for Weight Loss: What Plan Sponsors Need to Know*, Segal, accessed March 2023 <https://www.segalco.com/consulting-insights/new-drugs-for-weight-loss-what-plan-sponsors-need-to-know>

summarized in Figure 7. Note that 2023 is only for 6 months and, for comparison purposes in Figure 7, we have assumed annual costs will be twice these amounts.

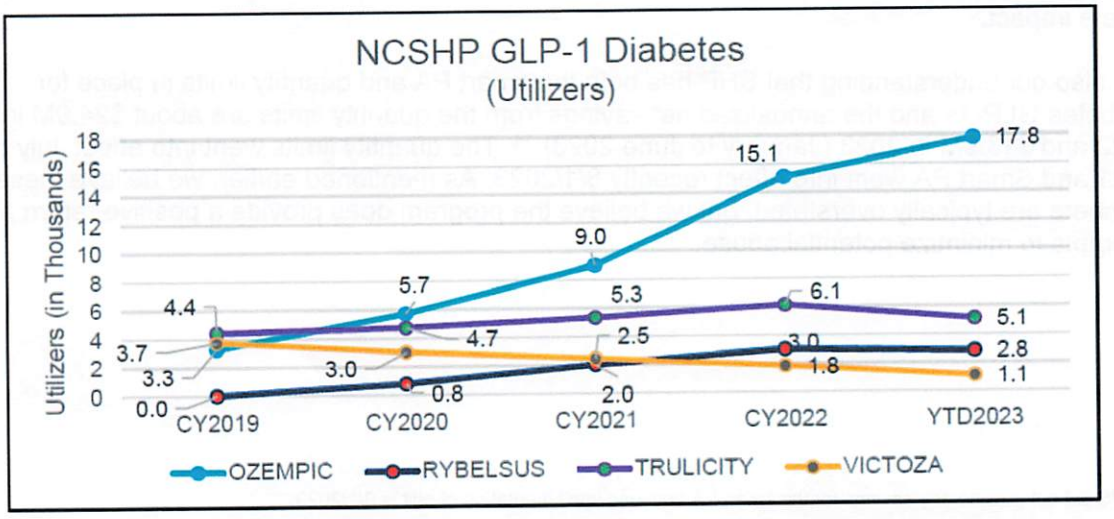
Figure 7



Regarding utilization, Ozempic accounts for the highest prescription volume in this class. It has been approved in higher doses that are heavily advertised for improved glucose control and weight loss. Ozempic 2mg has been associated with an average weight loss of 14.1 pounds over 40 weeks. Mounjaro is the newest drug in this class, with the most significant weight loss reported and is rapidly growing in market share. There are concerns that these drugs are being used for AOMs versus a portion of a treatment plan for diabetic patients. As we stated in the AOM section, without behavior modification, patients will gain back the weight when they stop taking the medication.

For SHP, Ozempic had the biggest increase in utilization from 2019 to 2023 going from 3,258 utilizers to 17,802 utilizers. Trulicity remains at a steady utilization and Rybelsus (which is the only oral GLP-1 medication available at this time) saw a big jump in utilization.

Figure 8



Overall, the number of utilizers has doubled since 2020 – from 14k to 28k members.

Note that Mounjaro® was approved in May 2022 and has a unique dual mechanism of action (may be even more effective than semaglutide or Ozempic in reducing weight). There was small utilization for Mounjaro in 2022 (259 utilizers) and in 2023 (571 utilizers), but we expect utilization to increase moving forward. The net costs for Mounjaro for 2022 was $509K and more than doubled in the first six months of 2023 at $1.15M.

Review of GLP-1 Drug Utilization Controls

As a result of the increased utilization combined with the potential off label use and the high cost, SHP decided to add CVS's drug utilization controls. Per CVS, they are offering a GLP-1, GIP-GLP-1 agonist PA with logic strategy. This Smart Prior Authorization (PA) offering targets antidiabetic GLP-1 agonists (e.g., Ozempic, Victoza) and GIP/GLP-1 agonists (e.g., Mounjaro).

How it works: Smart logic will be used to help screen out patients using these agents for the FDA-approved indication of diabetes. Smart logic will utilize both ICD diagnosis codes (if available) or prescription claims history to bypass PA requirements.

- If the claim has an ICD diagnosis code indicating use for diabetes, the claim will bypass PA requirements.
- If the patient has filled a prescription for at least a 30-day supply of an antidiabetic drug, excluding the requested drug at the same or other strengths, OR a diabetic supply, such as test strips, in the past 730 days, then the claim will also bypass PA requirements.

If the smart logic criteria are not met, the claim will reject and require prior authorization.

For claims rejecting for PA, confirmation of a diagnosis of type 2 diabetes will be required for approval. Chart notes or other documentation supporting a diagnosis of diabetes will need to be submitted to confirm diagnosis.

Review on Prior Authorization on GLP-1s for Diabetes

Segal has reviewed the criteria for the GLP-1/ GIP-GLP-1 diabetic medications and finds that the policy meets FDA and clinical guidelines. It is our understanding that there is no rebate impact.

It is also our understanding that SHP has both the smart PA and quantity limits in place for Diabetes GLP-1s and the annualized net savings from the quantity limits are about $24.9M in 2022 and $13.9M in 2023 (January to June 2023).[14] The quantity limits went into effect July of 2021 and Smart PA went into effect recently 8/1/2023. As mentioned earlier, we believe these numbers are typically overstated, but we believe the program does provide a positive return and attempts to minimize potential abuse.

[14] CVS did not provide any savings for the smart PA because implementation of edit is 8/1/2023.

Other ideas if SHP wants to consider stricter coverage for GLP-1s:

Since cost escalation are a major concern for our clients, some plans are considering implementing stricter coverage polices with example criteria below. Note that these thoughts are based on ideas and have not been vetted through the PBM (i.e., CVS) or reviewed for compliance with regulations, and may also have a negative rebate impact.

- Screen out logic requiring trial of at least one other antidiabetic drug in the past 730 days seems overly generous. Recommend a shorter look-back period of 365 days.
- For patients who do not meet screen out logic, PA criteria requiring diagnosis with chart note documentation is appropriate, though there is no time period defined for the lab diagnosis/chart note confirmation (recommend within the past 12 months).
- Other PBMs are also offering preferred Step Therapy policies to ensure that once a member meets the PA clinical criteria, the preferred GLP-1 is used before others are tried. This strategy, along with rebates, may help manage the rising costs associated with these products.
- Mandate the PBM to incorporate ICD-10 codes for coverage. If there is no ICD-10 diagnosis for diabetes, then initiate the prior authorization. CVS to confirm that they can do this operationally and confirm that they can continuously load the ICD-10 information.
- Other PBMs are also requiring more than one antidiabetic drug in the look-back period if one of the drugs is metformin. This may be due to metformin being used for conditions not related to diabetes (i.e., polycystic ovary syndrome).

What Are Other States/Plans Doing for AOMs & GLP-1s

- New research from the STOP (Strategies to Overcome & Prevent) Obesity Alliance in *Obesity* (journal) provides "a state-by-state analysis of State Employee Health Plan health care coverage for plan year 2020/2021 for obesity prevention and treatment, including preventive services and counseling, nutrition counseling, drug therapy, and bariatric surgery." We included a link to the journal article below, as well as a 2022 Urban Institute report, mentioned in a 2022 HealthPayer Intelligence (a health industry news source) article[15], which examines state employee health plan data sourced from the STOP Obesity Alliance.
  - Per the article, "the paper highlights trends in state employee health coverage between 2009, 2017 and 2021. Between 2009 and 2017, there was a positive trend in coverage of obesity related treatments but between 2017 and 2021 coverage plateaued for nutritional counseling and bariatric surgery and **declined for pharmacotherapy**." Due to the high cost of these drugs, there is a shift in the marketplace.
  - To access a quick map of states that cover anti-obesity drugs visit the STOP Obesity Alliance website.[16]
- Coverage for other obesity treatment options varies substantially across the country. Fifteen Medicaid programs cover anti-obesity medications in fee-for-service Medicaid, and only four additional programs cover anti-obesity medications under at least one Medicaid managed-

[15] https://healthpayerintelligence.com/news/state-medicaid-coverage-for-obesity-treatments-varies-widely
[16] https://stop.publichealth.gwu.edu/coverage

care plan. Only two states cover anti-obesity medications in benchmark Marketplace plans, and 16 state employee plans offer such coverage.

- Obesity Across America[17] (Urban Institute, February 17, 2022)
- p. 25: (figure 13) State-Level Employee Health Plan Coverage of Obesity Treatments, 2020–21

- States that cover anti-obesity drugs: Nevada, Texas, New Mexico, Kansas, South Dakota, Wyoming, Minnesota, Michigan, Kentucky, Tennessee, North Carolina, Virginia, New York, New Jersey, Massachusetts, Maine.[18]

- *Notes*: Coverage for pharmacotherapy was undetermined for Illinois, Missouri, Montana, North Dakota, Oklahoma, Oregon, and Vermont. Treatments for which coverage was undetermined were coded as "not covered." Undetermined coverage means information was unavailable or conflicting information was found in separate documents.[19] Also note that Segal has not audited this list and notes that at least one of the states listed, Texas, does not cover weight loss drugs.

- According to the Wall Street Journal's recent article, the prescription-drug benefit plan for state government employees in Connecticut now requires members to obtain anti-obesity drugs through Intellihealth, a Connecticut-based, anti-obesity medical practice that offers telehealth and app-based care.[20] The Intellihealth program provides coverage for weight loss drugs in a managed setting. According to the State's website, starting July 1, 2023, medications prescribed for weight loss or weight management will only be covered if they are prescribed by a Flyte physician. Flyte, Intellihealth's clinical services affiliate, is a medical weight loss program offered to eligible State health plan members and their enrolled family members.[21] It is a program that looks at proper prescribing, medical oversight and provides tools to improve diet and physical activity.

- Ascension Healthcare and University of Texas stopped or will stop covering anti-obesity drugs including Wegovy and Saxenda for its members.[22] There are some that are opting to increase copays like the University of Michigan's employee benefits who increase copays by more than double.[23]

- The IFEBP[24] 2022 Employee Benefits Survey found that 22% of plans covered prescription drugs for weight loss.

In general, it appears that most clients still do not cover anti-obesity medications today. There is high variability by state and the reasons to have or not have them covered are specific to each. Due to the amount of money and investment in this drug category, we would expect greater pressure of coverage to continue for our clients. If the costs get more reasonable, we would expect greater coverage and hopefully a long-term savings for our clients, but that is not expected in the near future.

[17] https://www.urban.org/sites/default/files/2022-02/obesity-across-america.pdf
[18] https://stop.publichealth.gwu.edu/coverage/medicaid
[19] https://stop.publichealth.gwu.edu/coverage/medicaid
[20] https://www.wsj.com/health/healthcare/employers-cut-off-access-to-weight-loss-drugs-for-workers-cb277a44
[21] https://carecompass.ct.gov/state/pharmacy/
[22] https://www.wsj.com/health/healthcare/employers-cut-off-access-to-weight-loss-drugs-for-workers-cb277a44
[23] NY Post article
[24] International Foundation of Employee Benefit Plans

Summary

The anti-obesity coverage question continues to be a very difficult task for many plans as there needs to be a balance between the high cost of these newer medications and the success of the weight loss outcomes and even sustaining the weight loss. For those that do cover AOMs currently, we find that they typically add prior authorization or step therapy edits and may also include some sort of behavior management coaching and other potential treatment options like nutrition counseling or exercise program. There are a few behavior management programs that come to mind that have various coaching philosophies like Trestletree, Vida Health, Virta Health (which may be diabetes specific), and Onduo. The high cost and known abuses of this drug category has also led some of our clients to remove coverage altogether or to implement much stricter coverage requirements.

Due to increased utilization, off-label use and high costs of the GLP-1 medications for both diabetes and obesity, Segal agrees with SHP's decision to add CVS's standard PA for all GLP-1s anti-obesity medications and non-GLP-1 medications, and CVS's standard smart claim edit offering on all GLP-1/ GIP-GLP-1 anti-diabetic medications.

Segal has also provided some custom criteria options. If SHP is considering any of the custom criteria, Segal on behalf of SHP or SHP will need to attain rebate impact (if any) from CVS to determine any financial impact and any customization operating costs. The SHP P&T and SHP's legal counsel/compliance team may also need to weigh in on custom criteria.

SHP should take a **comprehensive approach** to managing diabetes and obesity that includes both the pharmacy benefit and medical benefit perspective. SHP may want to consider the following strategies to help mitigate unnecessary cost and improve both quality of life and patient experience, while potentially leading to lower overall healthcare costs:

Diabetes Management

- Continue CVS's current step therapy programs that confirm a type 2 diabetes diagnosis and evaluate any changes to edits as they are presented.
- Evaluate and consider stricter criteria for GLP-1 medication coverage if allowed by SHP P&T, PBM and in compliance with all applicable rules and regulations.
- Evaluate and consider non pharmaceutical approaches to diabetes management and weight loss through SHP's current vendor partners or other vendors if needed.

Obesity and Weight Management

- Consider whether the plan should cover all AOMs. Some states have removed coverage for either the entire class or just the higher cost drugs; others have chosen to slowly introduce new AOMs as they are proven to be cost effective.
- Continue to cover AOMs tied with CVS's current prior authorization programs. Consider auditing PA approval rates to ensure policies are being followed and proper documentation is provided to support the decision.
- Cover AOMs but only through a comprehensive weight loss program (similar to State of CT strategy).
- Evaluate and consider stricter criteria for GLP-1 medication coverage if allowed by SHP P&T, PBM and in compliance with all applicable rules and regulations.

- Evaluate new drugs as they come to market and work with SHP P&T, Segal and CVS to determine if and when coverage should be considered for these expensive medications.
- Consider adding or creating a non-pharmaceutical weight loss strategy to the current benefit offering including nutritional support and behavioral modification therapy.

As we have mentioned throughout this memo, the costs of AOMs is going to continue to escalate, with the trend not being sustainable. If there were significant savings in medical claims to offset the high pharmacy cost, most plans would cover these drugs, but that has yet to be proven.

As more information becomes available regarding CVS's strategy for a broader weight loss coverage solution, Segal recommends SHP consider any new opportunities. It is imperative that the overall solution include a behavioral management component that will ensure that the weight loss is maintained. It would also be prudent for SHP to consider other approaches for the broader weight loss programs in the near future.

Segal is prepared to discuss this with you in detail and answer any questions you may have.

cc: Stuart Wohl, Segal
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