Compliance Considerations with GLP-1 Cost Containment Strategies

Introduction

Glucagon-like peptide-1 (GLP-1) is a hormone that is produced in the GI tract, pancreas, kidneys, and brain. This hormone has several roles, including triggering insulin release from your pancreas, blocking glucagon secretion, slowing digestion in the stomach, and increasing how full you feel after eating (satiety). GLP-1 affects areas of your brain that processes hunger and satiety, and GLP-1 medications work by mimicking this hormone. The satiety effect of GLP-1 medications reduces food intake, appetite, and hunger. These combined effects often result in weight loss.

GLP-1 medications have been used for years to treat Type 2 diabetes and are commonly covered by group health plans for this purpose. In the last few years, interest in these drugs for weight loss unrelated to the treatment of Type 2 diabetes has exploded. Plan sponsors are feeling significant pressure to cover these drugs strictly for weight loss purposes, and the challenge is the cost of GLP-1 medications in conjunction with the high percentage of obesity in this country. For example. some of the only GLP-1 drugs approved for weight loss, cost approximately $1,300 per month. With over 40% of adults categorized as obese, covering GLP-1s for weight loss can become prohibitively expensive for plan sponsors. To meet the high demand, but also manage costs, several approaches to covering GLP-1s for weight loss have emerged in the marketplace—each with their own compliance obligations and challenges.

Plan sponsors are feeling significant pressure to cover these drugs strictly for weight loss purposes, and the challenge is the cost of GLP-1 medications in conjunction with the high percentage of obesity in this country.

GLP-1 Weight Loss Only Coverage

With respect to covering GLP-1s for weight loss, plan sponsors have three general coverage options:

1. to exclude coverage for these medications for weight loss, which is generally permissible,
2. to fully cover these medications for weight loss under their major medical/ pharmacy plan, which is cost prohibitive, or
3. to provide coverage for weight loss with certain cost containment strategies.

Most employers fall into this third category given that they want to provide some level of coverage for weight loss, but it's imperative to be mindful of the cost to the plan. We focus our discussion here on those cost containment strategies and the compliance issues to consider for each.

Cost Containment Strategies to Cover GLP-1s for Weight Loss

Several strategies have developed to manage costs for covering GLP-1 medications for weight loss. Those strategies include, but are not limited to:

1. Covering GLP-1s on the major medical/pharmacy plan with significant medical management. Common medical management approaches include:
   - Step therapy, e.g., unsuccessful attempts at weight loss using other programs or medication
   - Prerequisite or simultaneous participation in an intensive behavior change program focused on nutrition, physical activity, and mental health support
   - Limiting quantity dispensed to a one-month supply
   - A body mass index (BMI) at a certain level
2. Covering GLP-1s for treatment of Type 2 diabetes on the major medical/pharmacy plan, and contracting with a separate Pharmacy Benefits Manager (PBM) or Third-Party Administrator (TPA) to manage coverage of GLP-1s for weight loss.
3. Employers make a dollar contribution to a very limited purpose Health Reimbursement Arrangement (HRA), which only covers GLP-1s for weight loss, often using certain qualifying criteria.

Compliance Considerations for Cost Containment Strategies

Tenure/Years of Service Requirements. Self-funded plans are subject to the nondiscrimination rules in Internal Revenue Code section 105(h), which generally prohibits discrimination in favor of a highly compensated individual in the provision of group health plan benefits. As a result, covering GPL-1s with a benefit-specific tenure or years of service requirement is problematic under IRS 105(h). Even with limited enforcement of this provision, this approach is expressly precluded under longstanding regulations.

Cost Sharing Strategies

Excluding Costs from Accumulating Toward the Deductible. An approach that excludes specific covered items or services from accumulating toward the participant's cost sharing limits is problematic, particularly for Health Saving Account (HSA)-compatible High Deductible Health Plans (HDHPs). Those plans cannot be administered in a compliant fashion if the participant's actual out-of-pocket costs exceed statutory limits, which would be the case where GLP-1 cost sharing did not accumulate toward the cost sharing limits.

Lifetime or Annual Limits. While the Affordable Care Act (ACA) permits annual and lifetime limits on non-essential health benefits, the nature of GLP-1 drugs is that an individual takes them for an extended period of time, if not indefinitely. As a result, plan sponsors should discuss with their clinical advisors whether covering these drugs for short periods is advisable. This type of plan design could incur significant plan costs without any long-term benefit to participants or to the financial stability of the plan.

Increased Coinsurance for GLP-1s. Increasing coinsurance for GLP-1s is a permissible cost containment strategy. Plan sponsors should be sure to effectively communicate coinsurance requirements in all plan materials—including any open enrollment documents and plan documents—and ensure participants have access to GLP-1 drugs on an ongoing basis subject to reasonable and consistent terms.

Conditioning Employer Contribution or Coverage on Weight Loss Program and/or BMI Threshold

Many employers are considering covering GLP-1s, either through an HRA, a separate PBM, or TPA, or as part of their major medical/pharmacy plan—but only for participants with a certain threshold BMI and/or eligible individuals who participate in a weight loss program. Regardless of how the coverage is provided, a requirement that eligible individuals participate in a weight loss program and/or have a BMI over a certain threshold functions as what is generally referred to as a disease management program. Plan sponsors are permitted to target certain individuals for participation in this program, which is something known as "benign discrimination". Requiring

individuals to disclose their BMI as a condition of participating in the program and receiving the coverage is a medical inquiry under the American with Disabilities Act (ADA), which is subject to certain rules. These rules include the requirement that the plan be voluntary, which means the incentive to participate—here, the amount the employer is willing to pay toward GLP-1s—cannot be "too high". Given the absence of clear regulatory guidance on what amount is "too high", a general rule of thumb based on prior guidance is 30% of the total cost of employee-only coverage.

Challenges With Providing Coverage Through an HRA or Separate PBM

HRA Coverage. A HRA is group health plan exclusively funded by employers to reimburse employees for qualified medical expenses. When an employer seeks to provide financial assistance to employees for tax deductible medical expenses, whether they know it or not, they are usually creating an HRA. There are a number of compliance requirements when providing GLP-1 coverage through an HRA, including the ERISA plan document requirement, the application of Internal Revenue Code section 105(h) nondiscrimination requirements, the application of HIPAA's privacy and security rules, and potential PCORI fee implications where the underlying medical plan is fully insured. In addition, the HRA's eligibility and coverage provisions, and reimbursement processes must be clearly documented and communicated. The HRA may also need to be designed to interact with HSA-eligible HDHPs to avoid impacting the HSA eligibility of those enrolled in an HDHP plan. This generally requires that HRA reimbursements are made on a post-deductible basis. In addition, the plan sponsor would have to consider how the HRA administration interacts with the major medical plan administration to ensure all costs are appropriately accruing to applicable cost sharing limits.

Carve Out PBM Coverage. Where an employer decides to provide coverage through a separate carved out PBM, the challenges can include: employee communication, proper administration of cost sharing and integration with the major medical/pharmacy plan, difficulty obtaining a compliant plan document, and possible problems complying with annual pharmacy reporting requirements where the PBM is unwilling to support reporting and/or data might be difficult to obtain.

Some Good News

While we have focused here on the challenges of providing GLP-1 coverage for weight loss, the good news is that these issues are not insurmountable. A compliant plan design and administration does, however, require (1) advisors that are well versed in the topic from both a compliance and a clinical perspective, (2) vendor partners who will support the proper administration of any plan design, and (3) a solid understanding of your organization's financial objectives and risk tolerance as they relate to your group health plan.

Excluding Coverage, Essential Health Benefits, and Health Saving Account (HSA) Eligibility.

In order to understand the full landscape of GLP-1 compliance issues (not just cost containment for weight loss coverage), it is important to understand what is permitted, what is required, and what is prohibited. To that end, note that group health plans are only required to cover ACA preventive care items, and GLP-1 drugs are not on that preventive care coverage list. Another legal framework that might mandate certain coverage is the ADA. Under the ADA, a plan cannot include a disability-based plan design distinction and, as a result, may not be permitted to exclude certain drugs or services. However, obesity in and of itself is not an ADA-recognized disability and, in any event, the ADA contains a cost exemption that allows plans to avoid providing certain coverage that is prohibitively expensive. As a result, there is no mandate—under the ACA or otherwise—that requires group health plans to cover this class of drugs for weight loss purposes.

On a somewhat related issue, the ACA generally requires individual and small group health plans to cover certain categories of benefits deemed essential, commonly known as essential health benefits. While large group health plans are not subject to these requirements, they are prohibited from putting lifetime and annual limits on

essential health benefits. To date, GLP-1s have not been designated as an essential health benefit under the ACA, which means (1) there is no mandate to cover the medication in the individual and small group market, and (2) large group plans can place annual limits on these drugs (but see note below). Whether it is clinically advisable to do so is another issue.

Finally, it is important to note that group health plans can generally provide coverage below the deductible for GLP-1 drugs without impacting a participant's HSA eligibility, meaning employer plan sponsors can contribute toward the cost of these medications before a participant has met their deductible on an HSA-eligible HDHP. This is permissible because these medications are considered preventive care under the IRS rules on HSA-eligible HDHPs. These rules generally require participants pay out-of-pocket until they meet their deductible, with an exception for certain preventive care. Do not, however, confuse this rule with the ACA preventive care mandate. The IRS rule is not a requirement to cover these medications without cost sharing; rather it allows employer plan sponsors to contribute to the cost of the medications below the deductible, but employer plan sponsors can (and likely should) require participants share in the cost of the medication.

Pending Guidance That Could Impact Employer Decisions

The Departments of Labor, Treasury, and HHS recently issued FAQ guidance stating that the ACA essential health benefits requirement referenced above, which applies to individual and small group market plans and designates that all prescription drugs covered under the plan are deemed an essential health benefit, may be extended to the large group market—including large self-funded plans. Should that happen, plan sponsors covering GLP-1s for weight loss will need to consider the impact of those medications being designated as essential health benefits—and not subject to lifetime or annual limits—on their cost containment strategies.

Conclusion

The use of GLP-1s is evolving rapidly and may include not only treatment for Type 2 diabetes but also conditions such as sleep apnea and cardiovascular disease, which ultimately may complicate how group health plans, PBMs, and TPAs draft and administer plan exclusions. In addition, the solutions available in the marketplace for weight loss coverage as well as the regulatory landscape on this topic are shifting rapidly. Alliant's Compliance, Clinical, and Pharmacy teams will continue to monitor this situation and provide updates and strategic guidance as you consider and develop your own best practice approach on this issue.

Disclaimer: This material is provided for informational purposes only based on our understanding of applicable guidance in effect at the time and without any express or implied warranty as to its accuracy or any responsibility to provide updates based on subsequent developments. This material should not be construed as legal or tax advice or as establishing a privileged attorney-client relationship. Clients should consult with and rely on their own independent legal, tax, and other advisors regarding their particular situations before taking action. These materials and related content are also proprietary and cannot be further used, disclosed or disseminated without express permission.

Alliant

CA License No. 0C36861
© 2024 Alliant Insurance Services, Inc.