Gallagher

Compliance Directions

Compliance Considerations on GLP-1 Limitations

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In the past two years, plan sponsors have seen a rapid uptick in usage of a class of drugs commonly called glucagon-like peptide 1 (GLP-1) agonists for weight loss, causing their prescription drug claims to increase substantially. This trend is likely to continue over the next few years with new GLP-1s coming onto the market. As plan sponsors prepare for the 2025 plan year, most are deciding whether to limit coverage, place utilization management restrictions, or carve them out to a different third-party administrator (TPA). Below we discuss the compliance considerations that plan sponsors face when modifying their prescription drug coverage, including GLP-1s.

Background

There are a number of approved GLP-1s on the market. Some are approved for diabetes, while others are approved for weight loss, lowering the risk of stroke, heart, liver, and kidney disease, and decreasing blood pressure and cholesterol levels. The market will continue to expand with new FDA approved uses expected in the next few years and the release of new products. Manufacturers are also seeking new approved uses for GLP-1s that include sleep apnea, osteoarthritis, and heart failure.

When designing prescription drug benefits, there are a variety of compliance laws that impact whether and how an employer can restrict, manage, or eliminate coverage. The primary considerations are the Health Insurance Portability and Accountability Act (HIPAA) nondiscrimination rules, the Americans with Disabilities Act (ADA), and the Patient Protection and Affordable Care Act (ACA).

Although not a compliance issue, plan sponsors should also consider the practical implications of limiting GLP-1 coverage for a particular condition, which can impact the plan's receipt of rebates since most pharmacy benefit managers require a plan to cover all of the drug's uses to qualify for associated rebates.

HIPAA Nondiscrimination

HIPAA prohibits group health plans from discriminating on the basis of a health factor, including health status, medical conditions, claims experience, receipt of health care, and medical history. While HIPAA does not require a group health plan to provide particular benefits or prevent a plan from establishing limits or restrictions on the

amount, level, extent, or nature of benefits for similarly situated individuals, benefits that are provided must be uniformly available to similarly situated individuals, and restrictions must apply uniformly and not be directed at individual participants based on a health factor. Thus, a plan may limit or exclude certain types of drugs if the limit or exclusion applies to all similarly situated individuals and is not directed at individual participants based on a health status related factor.

In addition, the HIPAA regulations provide a safe harbor for plan amendments that impose limitations or exclusions if the amendment applies to all individuals in one or more groups of similarly situated individuals and is effective no earlier than the first day of the first plan year beginning after the amendment is adopted.

GLP-1 Considerations: Because GLP-1s treat health conditions, and a plan sponsor's decision is likely at least partially a response to increased costs to the plan, sponsors should consider placing any utilization management requirements or eliminating coverage with an effective date at the beginning of the plan year and apply the provision to all similarly situated individuals.

ADA

The ADA prohibits employers from discriminating on the basis of disability in the provision of health benefits to employees. A distinction is "disability-based" if it singles out a particular disability, a discrete group of disabilities, or disabilities in general. Within that prohibition, it is possible for distinctions to be made without violating the ADA if 1) the distinction is applied equally to all employees, or 2) if the employer demonstrates that its plan is "bona fide" and the plan is not a "subterfuge" to evade the purposes of the ADA.

Under the first exception, a distinction is not disability-based if it applies to all covered employees equally. The EEOC Interim Enforcement Guidance on the topic offers examples of permissible plan provisions, such as exclusions or limitations for eye or dental care, experimental drugs and treatments, elective surgeries, and procedures not exclusively or near-exclusively used for the treatment of a particular disability. The Interim Guidance also provides examples of impermissible distinctions – caps on benefits for treatment of AIDS, provisions that affect a discrete group of disabilities (e.g., cancer or kidney disease), and those that impact a disability in general (e.g., noncoverage of all conditions that substantially limit a major life activity).

Under the bona fide plan exception, the employer must demonstrate that it sponsors a bona fide plan by paying benefits and accurately communicating those benefits to employees, and that the plan is not a subterfuge to evade the purposes of the ADA by justifying the provision on sound actuarial principles.

GLP-1 Considerations: As GLP-1 uses increase to treat more disabilities under the ADA, the litigation risk of limiting GLP-1 coverage will also increase. While many of the diagnoses that GLP-1s treat are disabilities, most courts do not recognize obesity as a disability unless caused by an underlying health condition. However, there are jurisdictions that treat obesity a disability even when not connected to an underlying health condition. Moreover, some state and city laws define obesity as a disability.

Plan sponsors that limit plan coverage only for weight loss still carry a risk under the ADA because many of the disabilities that GLP-1s treat are a result of an individual's obesity. Plan sponsors that limit all coverage, may attempt to reduce their litigation risk by demonstrating that the plan is bona fide by accurately communicating plan benefits, and show that the plan is not a subterfuge for evading the ADA by ensuring the decision is based on actuarially sound data.

ACA

The ACA does not require the coverage of specific prescription drugs, except in the case of the preventive care mandate, which does not include GLP-1s. However, there are ACA considerations when carving out the utilization management to third parties for GLP-1s. Most insurers and TPAs will not implement utilization management programs only on GLP-1s. Rather, they will implement broad programs over multiple classes of high-cost drugs. Employers that are not interested in applying such broad reviews to avoid substantial disruption on prescription drugs that are not causing an increase in spending (although such programs are likely to avoid as much scrutiny under HIPAA and the ADA), may be interested in carving out the GLP-1 coverage to a separate TPA who can handle utilization management.

Carving out the coverage of GLP-1s to a third party that can manage the process is not problematic; however, prescription drugs obtained in-network are considered essential health benefits (EHBs), and non-grandfathered group health plans must accrue a participant's cost sharing toward the plan's out-of-pocket maximum and are prohibited

from placing annual or lifetime limits on those EHBs. As discussed in our April 2024 Directions article, *New Guidance Will Bring Changes to Prescription Drug Carve-Outs*, some vendors may have interpreted prior guidance to allow group health plans to treat certain prescription drug costs as non-EHBs, including drugs for weight loss, and not counting a participant's cost sharing toward the plan's out-of-pocket maximum. However, in April 2024, the Centers for Medicare and Medicaid Services (CMS) clarified its stance and will require individual and small group plans to count the costs toward the out-of-pocket maximum for plan years beginning on or after January 1, 2025. The Departments of Labor, Health and Human Services, and the Treasury (the Departments) also announced their intent to propose regulations requiring the same for large fully insured and self-insured plans. To date, those proposed regulations have not been issued; however, understanding the Departments' intent, plan sponsors should consider counting prescription drug costs obtained in-network toward the plan's out-of-pocket or expect to amend that design once final guidance is issued. Annual or lifetime limits will also need to be removed at that time.

GLP-1 Considerations: Plan sponsors of small group plans should count in-network participant cost sharing toward the plans' out-of-pocket maximums and avoid placing annual or lifetime limits on the drugs. Large fully insured and self-insured plans should consider the same design. If a large employer chooses not to count the GLP-1 costs toward the plan's out-of-pocket maximum at this time, they should be prepared to comply once regulations are issued.

Action Items

Plan sponsors that choose to limit coverage to the GLP-1 drugs should consider:

- Amending the plan at the beginning of the plan year to secure the benefit of the HIPAA nondiscrimination safe harbor;
- Meeting one of the ADA exceptions if limitations will be placed on access to the GLP-1s for individuals with defined disabilities or conditions that are the underlying cause of a disability; and
- Plans that will continue to cover the drugs, even if limited, should accumulate the participant costs for the drugs toward the plan's out-of-pocket maximum.

The intent of this article is to provide general information on employee benefit issues. It should not be construed as legal advice and, as with any interpretation of law, plan sponsors should seek proper legal advice for application of these rules to their plans.