# Compliance Insights

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# C a ce C de a
# GLP-1 C C a e S a e e

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 categori ed 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.

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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

containment strategies and the compliance issues to consider for each.

## Co Con ainmen S ra egie o Co er GLP-1 for Weigh Lo

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.

## C C C C

**Te e/Yea f Se ce Re e e .** 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.

### Co Sharing S ra egie

**E c d C f Acc a T a d e Ded c b e.** 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 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.

## C C A B

**HRA C e a e.** 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