EMPLOYERS HEALTH®

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Female Libido Drug Raises Clinical and Legal Considerations

How should plan sponsors handle this drug?

With the recent approval of Addyi (flibanserin) for the sudden and unexplained loss of libido for premenopausal women, plan sponsors must weigh clinical and legal considerations. There are very important questions over Addyi's low efficacy, concerning side effects, and the potential for gender discrimination. From a clinical perspective, Employers Health recommends plan sponsors that cover male erectile dysfunction (ED) drugs, such as Viagra and Cialis, implement prior authorization criteria to ensure proper use of the new medication. For plans that do not cover ED drugs, Employers Health recommends not covering Addyi. From a legal perspective, plans must remember that they are subject to discrimination rules, including Title VII, that prohibit an employer from discriminating with respect to gender. Thus, plans that cover ED drugs, such as Viagra and Cialis, seeking to exclude or implement a process to ensure appropriate utilization of Addyi based on efficacy or safety concerns must apply the same efficacy and safety requirements the plan maintains for other drugs.

Clinical Background

Based on how Addyi works on the brain, the "pink pill" needs to be taken nightly for two to four weeks to see an effect. Additionally, the data show only one in ten women perceive a benefit from this medication, which was a modest 0.5 more "sexually satisfying events" per month compared to placebo. This relatively small effectiveness has formulary decision makers wondering if coverage is necessary and prescribers wary of providing access to their patients to the $11,680 per year drug.

The Food & Drug Administration (FDA) had rejected the medication twice before (in 2010 and 2013) due to the concerns, but as a result of a powerful marketing and advocacy campaign by the drug manufacturer and women's groups, Addyi was approved despite no new beneficial evidence. In fact, a stronger link was shown for increased risk of harm and drug interactions with alcohol and oral contraceptives. To maneuver around these issues, the FDA approved the medication for daily use at bedtime and requires prescribers to undergo specially certified training to ensure women will abstain from alcohol permanently while on Addyi. Still the potential for off-label use exists.

At a minimum, Addyi should have prior authorization criteria in place to ensure proper use of the new medication. For example, premenopausal women diagnosed with hypoactive sexual desire disorder (HSDD) that are abstaining from alcohol should be the only women allowed to fill a prescription for Addyi. For plan sponsors that must cover Addyi, limiting the initial approved quantity to eight weeks then evaluating for symptom improvement is a sound utilization strategy to relate back to the efficacy shown in clinical trials. As of this article, the general theme of our employers is parity coverage to ED drugs. Thus, if a plan sponsor covers ED drugs, then Addyi will likely be covered, and vice versa.

Legal Perspective

In considering an approach to exclude, limit or manage a particular treatment or medication, plan sponsors must remember that they are subject to discrimination rules, including Title VII, that prohibit an employer from discriminating with respect to any terms and conditions of employment on the basis of race, gender, age, national origin, religion, etc. These rules are enforced by the Equal Employment Opportunity Commission

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(EEOC). To aid employer compliance, the EEOC maintains a compliance manual. While most think of the EEOC's regulatory actions to primarily focus on actions of the employer relative to the workplace and the hiring and firing of employees, the EEOC devotes an entire chapter of its compliance manual to employee benefits. However, given the recent cases filed by the EEOC challenging employer wellness programs, the regulatory reach of the EEOC in this area may not surprise many readers. Pursuant to the EEOC Compliance Manual, health insurance benefits must be provided to participants without regard to the race, color, sex, national origin, or religion of the insured, but perhaps more problematic, an employer must also ensure that the terms of its health benefits are non-discriminatory.

Not surprisingly the manual contains a general prohibition against providing different coverage to men and women where both men and women are, or could be, affected by the same condition or helped by the same treatment. That said, evaluating a discrimination charge becomes nuanced when the employer's rationale for not offering coverage arises from generally accepted medical criteria. As with all discrimination claims, even if a practice is not facially discriminatory, it may be deemed discriminatory if it yields discriminatory results. Employers may be able to evade such claims if their rationale arises from generally accepted medical criteria. In the face of efficacy and safety concerns, the EEOC requires that a plan sponsor making coverage decisions based on "efficacy" apply the same methodology that it relies on to evaluate treatments for all conditions.

In light of a potential discrimination claim, plan sponsors seeking to exclude Addyi may assert two theories to reinforce their approach. First, a plan sponsor may assert that Addyi is unique and it does not treat the same condition in men; thus, parity is not possible or necessary. Second, a plan sponsor may seek to exclude Addyi based on safety and efficacy concerns. Plan sponsors relying on a rationale that the Addyi and ED drugs are dissimilar must use caution. Despite different mechanisms of operation, a claimant may argue that the medications treat an equivalent condition – the inability to maintain satisfying intimate relationships. While perhaps not a successful claim, it is important to note that regardless of who would prevail on such a claim, the costs, direct and indirect, of a plan sponsor to defend such an accusation must be taken seriously. What is more, given marketing and lobbying efforts and press received by Addyi, plan participants may be unable or unwilling to discern the difference between drugs for ED and Addyi.

To reduce the risk of a successful discrimination claim, plan sponsors can take several steps. Plan sponsors covering ED drugs, such as Viagra and Cialis, seeking to exclude Addyi based on efficacy or safety concerns must be cautious that Addyi is excluded using the same efficacy and safety requirements it maintains for other drugs. Given Addyi's safety and efficacy concerns, a prior authorization would appear appropriate. A more drastic course, removal of ED drugs, likely eliminates potential parity, thus reducing risk. Plan sponsors must judge for themselves what risk they are willing to incur when confronting this or any other new drug with discriminatory implications. But plan sponsors may also use this as an opportunity to review their treatment of existing covered drugs, in this case potentially excluding ED drugs, or requiring prior authorizations for current and/or new drugs, in this case ED drugs and Addyi.

The EEOC Compliance Manual can be found here: http://www.eeoc.gov/policy/docs/benefits.html#B. Health Insurance

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