Workers' Comp

Implications of Epidiolex FDA Approval on Workers' Compensation

September 5, 2018
4 MIN READ
Author profile image

Dr. Mitch Freeman, Pharm.D.

Chief Clinical Officer

Learn how the recent FDA approval of Epidiolex might impact the future of pain management in workers' compensation.

In June 2018, the Federal Drug Administration (FDA) approved Epidiolex, the first plant-derived cannabinoid medicine in the United States. With several states already moving toward legalization of medical marijuana, this is a major step for the federal government. Until this point, states and the federal government were at odds about whether marijuana should be legalized for medicinal purposes; most states currently have some form of medical marijuana program, while the federal government still considers marijuana a Schedule I drug. With federal approval of this drug comes several questions for the workers' compensation industry. To better understand the implications of Epidiolex, let's first review what the drug is and why its approval marks a turning point for the United States.

What is Epidiolex?

Epidiolex is an oral, plant-derived cannabinoid medication approved for use in severe childhood epilepsy cases. It is the first-ever cannabis-based drug to be approved by the FDA. As is required for FDA approval of any drug in the United States, the approval of Epidiolex involved several controlled clinical trials to prove its efficacy and safety in treating seizures. The FDA has previously approved three synthetic, cannabis-like drugs: Marional, Syndros and Cesamet. However, these drugs are not made from the cannabis plant itself; Epidiolex, on the other hand, is derived directly from the cannabis plant, which makes this approval particularly significant. In addition, Epidiolex only utilizes the cannabidiol (CBD) cannabinoid from the marijuana plant, meaning that the drug does not cause the "high" typically associated with marijuana products containing delta-9-tetrahydrocannabinol

(THC).

How Might Epidiolex's Approval Change Federal Legalization?

Marijuana is currently a Schedule I drug in the United States, meaning that it is considered to have a high risk of abuse and no clinical benefit. However, researchers were able to prove Epidiolex's clinical benefit through extensive clinical trials, which points to a possible rescheduling for marijuana. The last petition to reschedule the drug was denied in April 2017, but Epidiolex may require the DEA to reschedule the ingredient CBD in order to become commercially available. Additionally, Epidiolex is currently approved only for seizures, but FDA approval will likely allow for the expansion of indications and access to the drug for further trials. As more evidence is collected for the benefits of CBD medications, we expect to see eventual expansion into treatment for conditions common in workers' compensation claims.

What Does FDA Approval of Epidiolex Mean for Workers' Compensation?

There are several important considerations for workers' compensation in relation to the approval of Epidiolex. In the wake of the opioid crisis, medical marijuana has been a hot topic in the workers' compensation industry as a possible alternative for chronic pain treatment. With nearly 49,000 overdose deaths in 2017 (provisional data) attributed to all types of opioids, 19,000 of which are attributed to prescription opioids, the potential of alternative treatment is even more critical. Although Epidiolex is not currently available as a treatment for conditions common in workers' compensation, FDA approval of Epidiolex is the first step to clinically proving CBD medications as potential alternatives to opioids and subsequently legalizing these medications for the treatment of pain. Another consideration for insurers and employers is the currently complicated landscape of reimbursement for medical marijuana. As of now, each state has its own stance on medical marijuana legalization and subsequent reimbursement, most of which is vague or conflicting. However, with the approval of Epidiolex, much of this guesswork will likely be reduced, if not eliminated. If a drug is FDA-approved, it can be dispensed in pharmacies, assigned a National Drug Code (NDC) and run through Pharmacy Benefit Managers. If this FDA-approved formulation becomes available to workers' compensation patients, insurers will be able to control and cover this drug similarly to any other medications used to treat work-related injuries. Finally, there has been much debate on how marijuana legalization increases on-the-job injuries due to marijuana intoxication. Although this is still a concern with the legalization of recreational marijuana, Epidiolex does not cause any psychoactive effects. Again, although Epidiolex is not currently approved for treatment of pain, the hypothetical expansion of treatment would mean that those injured workers using the drug would not face the hazard of workplace injuries due to marijuana intoxication.

How Might the Future Look for Medical Marijuana in the United States?

Several possible outcomes could result from the approval of Epidiolex. In the near future, we expect additional trials and an expansion of approved conditions for treatment with Epidiolex. Additionally, this approval signals the potential end for medical marijuana dispensaries and the beginning for drug manufacturers to develop additional CBD medications. As stated earlier, this will allow for greater control by insurers and the PBMs that serve them. Finally, we expect gradual decriminalization of marijuana in general, since continued state recreational and medical legalization will likely lead to overall federal legalization. The approval of Epidiolex is a major step for the federal government, but further expansion of legalization will still likely take years. Clinical trials alone can take several years and the process to legalize will likely be complicated.



©2022 Enlyte Group, LLC.

mitchell | genex | coventry