History

Marijuana (cannabis sativa) has been utilized for purported medicinal purposes for thousands of years. Aside from historical references indicating that Egyptians were utilizing marijuana for the treatment of glaucoma and inflammation, Chinese, Greek and Indian cultures are also credited with using marijuana for more than 100 human ailments. In more recent time, the use of the drug was severely curbed in 1937 with the introduction of the Marijuana Tax Act, which levied taxes on the sale of marijuana and marijuana products (e.g. hemp). The legal use of marijuana for medicinal purposes on the federal level came to a distinct end in 1970 with the introduction of the Controlled Substances Act, which classified marijuana as a Schedule I substance. Schedule I products are considered to have high abuse potential, no accepted medical use and a lack of accepted safety data. Since 1970, there have been numerous failed petitions to reclassify marijuana as a Schedule II drug as the use of marijuana for medical purposes remains illegal at the federal level. The first state in the U.S. to legalize the use of medical marijuana since the introduction of the Controlled Substances Act was California in 1996.

Oregon and Washington passed initiatives in 1998, followed by Maine in 1999. As of July 2014, 23 states and Washington, D.C. have passed laws legalizing medical marijuana. Each state has its own limits for usable amounts and the number of plants that may be owned, as well as fees associated with medical marijuana use.

Figure 1. Medical marijuana possession limit by state*

<table>
<thead>
<tr>
<th>State</th>
<th>Year Legalized</th>
<th>Possession Limit (at any one time)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alaska</td>
<td>1998</td>
<td>1 usable ounce, 6 total plants</td>
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<tr>
<td>Arizona</td>
<td>2010</td>
<td>2.5 usable ounces, up to 12 plants</td>
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<tr>
<td>California</td>
<td>1996</td>
<td>8 usable ounces, up to 18 plants</td>
</tr>
<tr>
<td>Colorado</td>
<td>2000</td>
<td>2 usable ounces, 6 plants</td>
</tr>
<tr>
<td>Connecticut</td>
<td>2012</td>
<td>One-month supply (specifics undetermined)</td>
</tr>
<tr>
<td>Washington, D.C.</td>
<td>2010</td>
<td>2 ounces, dried</td>
</tr>
<tr>
<td>Delaware</td>
<td>2011</td>
<td>6 usable ounces</td>
</tr>
<tr>
<td>Hawaii</td>
<td>2000</td>
<td>3 usable ounces, 7 plants</td>
</tr>
<tr>
<td>Illinois</td>
<td>2013</td>
<td>2.5 usable ounces (during 14 day period)</td>
</tr>
<tr>
<td>Maine</td>
<td>1999</td>
<td>2.5 usable ounces, 6 plants</td>
</tr>
<tr>
<td>Maryland</td>
<td>2014</td>
<td>30 day supply, amount to be determined</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>2012</td>
<td>60 day supply for personal medical use</td>
</tr>
<tr>
<td>Michigan</td>
<td>2008</td>
<td>2.5 usable ounces, 6 plants</td>
</tr>
<tr>
<td>Minnesota</td>
<td>2014</td>
<td>30 day supply of non-smokable product</td>
</tr>
</tbody>
</table>

* Table adapted from Summary Chart: 23 States and DC that have enacted laws to legalize medical marijuana. www.ProCon.org
Commercially available products

Currently, only two commercially available cannabinoid-based medications, Marinol® (dronabinol) and Cesamet® (nabilone), are FDA approved for the treatment of nausea/vomiting that is non-responsive to traditional anti-nausea agents; Marinol is also FDA approved for the treatment of anorexia secondary to AIDS. These agents represent the only FDA approved medications that contain a synthetic version, or chemical precursor, of one of many active compounds found in marijuana. Not yet approved in the United States, but widely utilized in Europe, Australia and Canada, Sativex® is an oromucosal spray containing two active compounds found in marijuana, delta-9-tetrahydrocannabinol and cannabidiol. Sativex is currently utilized for the treatment of muscle spasticity secondary to multiple sclerosis. The drug’s manufacturer, GW Pharmaceuticals, is currently conducting Phase III clinical trials in an effort to gain FDA approvals in the United States.

Research

Proponents of medical marijuana have indicated that positive benefits exist in the treatment of several medical conditions, including AIDS associated pain and wasting, multiple sclerosis, cancer-related nausea and wasting, glaucoma, epileptic seizures, migraines, chronic pain and persistent muscle spasms. Clinical research indicates that medical marijuana may be effective in treating pain that is non-responsive to other pain-relieving therapies. Although these studies mainly focus on cancer-related pain, proponents claim that medical marijuana may be useful in non-cancer pain as well. Of the larger clinical studies conducted, some have indicated a potential benefit in the use of medical marijuana for pain management. One such randomized, placebo-controlled trial conducted in 2007 with 125 patients indicated that participants utilizing marijuana for medical purposes reported statistically significant reductions in pain scores, as well as improvements in secondary outcome measures of sleep and neuropathic pain symptoms. A similar study conducted in 2008 in 38 patients and published in the Journal of Pain reported that smoking marijuana led to significant analgesic response while exhibiting minimal psychoactive side effects. Conversely, opponents of legalizing marijuana for medical purposes argue that the benefits of cannabis for treatment

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* Table adapted from Summary Chart: 23 States and DC that have enacted laws to legalize medical marijuana. www.ProCon.org
of legitimate medical conditions are largely over-shadowed by the high number of potential risks. Marijuana-related adverse effects, such as impaired respiratory function (when smoked chronically), increased levels of anxiety with high dose use, and impaired cognitive ability detract from the potential benefits observed. Unfortunately, clinical trials offer mixed results regarding the effectiveness of marijuana for medicinal purposes; may indicate a lack of clear benefit or are not well structured. On a practical level, the very nature of state-permitted self cultivation of marijuana for medicinal purposes eliminates the standardization and purification standards set forth by the FDA for U.S. approved drug products. Given geographical differences in plant location, species variability and individual growth conditions (e.g. exposure to sunlight, amount of watering, etc.) it would be exceedingly difficult for prescribers to systematically “prescribe” a given amount/strength of medical marijuana for a given ailment. This lack of standardization would practically negate the ability to perform clinical trials that are generalizable to the public.

Although a literature search reveals that over 2,000 studies have been conducted on the use of marijuana for medical purposes, federal restrictions and the drug’s Schedule I designation continue to result in the publication of relatively small studies with insignificant power and robustness resulting in a lack of serious consideration by the medical community. It is possible that an expansion in the magnitude of trials conducted to investigate the use of marijuana for medical purposes may be approaching; however, several factors, including an unreceptive political climate, continues to provide a barrier in the ability to conduct large, well designed clinical trials.

**The medical community**

Despite conflicting clinical information, several organizations within the medical community have publicly endorsed the use of marijuana for its medical potential, including the American Academy of Family Physicians, the American Public Health Association, the American Nurse Association, the American College of Physicians and the New England Journal of Medicine, versus benefit of medical marijuana when considering the health effects associated with the process of smoking. Marijuana use via the pulmonary route may be associated with several histopathological changes in the lungs, including squamous metaplasia and basement membrane thickening. As carcinogenic compounds are found in marijuana, some clinical trials are attempting to demonstrate the benefit of other delivery mechanisms, such as transmucosal administration, which may avoid the negative health effects of the pulmonary route.

**The public**

Similar to the medical community, the general U.S. population continues to exhibit mixed feelings on the use of marijuana for legitimate medical purposes. A 2010 Gallup poll showed that a record 46 percent of Americans were in favor of legalizing marijuana. When asked specifically about the use of marijuana for medical purposes, 70 percent of Americans say that they favored making marijuana legally available for doctors to prescribe in order to reduce pain and suffering.

Recently, a poll conducted by a medical marijuana advocacy group indicated that 54 percent of physicians interviewed agreed with marijuana legalization, while 28 percent and 18 percent felt they disagreed with legalization or had no clear opinion, respectively. Similarly, an online poll conducted by WebMD and Medscape in 2003 found that 75 percent of physicians and 90 percent of nurses favored the use of marijuana for medicinal purposes.
Several others have advocated for controlled clinical trials (not legalization), including the American Medical Association (AMA), the American Cancer Society and the American Academy of Pediatrics. Historically, the AMA’s standpoint has been that of no scientific evidence to support changing marijuana’s Schedule I status. However, in late 2009, the AMA released a statement calling for a review of medical marijuana’s status with the goal of facilitating increased clinical research on cannabinoid-based medicines. This shift in the AMA’s position is indeed aligned with changing societal attitudes towards the potential benefits of using cannabinoid-based products, such that there is general agreement that for certain situations – wasting syndrome in AIDS and intractable nausea and vomiting in cancer treatment – use would be acceptable when other treatments have failed. The medical community continues to evaluate the risk.

Insurance

As more states continue to allow the use of medical marijuana for the treatment of certain conditions, including pain, issues are expected to arise in how workers’ compensation payers will handle claims for medical marijuana prescribed for the treatment of work-related injuries. Unfortunately, current federal thinking on the use of marijuana has left the courts uneasy about ruling in favor of legalized marijuana use for medicinal purposes at the state level. In a pivotal move in May 2014, a New Mexico Court of Appeals upheld a previous workers’ compensation court ruling (Vialpando vs. Ben’s Automotive Services) mandating that the injured worker’s medical marijuana be compensated under his workers’ compensation claim; appellate Judge James Wechsler indicated that the employer and carrier had not called out a specific federal law that would have been violated by the payment for medical marijuana. Although the decision in this case may have been made on a legal technicality, it may “fuel the
towards the argument that medical marijuana may be less addictive and less expensive than potent opioids (i.e. Oxycontin); however, significant data is lacking to substantiate this claim. Opponents to the legalization of marijuana cite various concerns including lack of quality control and long-term safety studies, as well as the availability of treatment alternatives. Certain states have included provisions in their legislation which indicate that the law does not require insurance companies to cover the cost of medical marijuana.

**Employers**

The use of medical marijuana presents significant issues for the workplace. Even in states where use may be legal, use in the workplace is not protected and may prevent an injured worker from returning to work. Many patients experience difficulties in the workplace as employers struggle with the appropriateness of allowing patients utilizing marijuana to continue performing regular work duties. Significant differences exist between states with regard to employee/employer rights. Legislation in New Jersey, for example, indicates that patients utilizing medical marijuana are not subject to criminalization; however, the law indicates that employers may terminate an employee if an employment-drug screen yields a positive test result. It is apparent that employers continue to struggle with allowing the use of a federally illegal substance in the workplace for purported medicinal purposes. A prudent path for employers to take would be to establish a clear position on the issue of medical marijuana use by employees and craft a policy that communicates their position effectively.

**Government**

While significant variability exists among the various states that have legalized marijuana for medicinal purposes, some countries, such as Canada, have taken a centralized approach to the production and dispensing of such products in an effort to standardize treatment from patient to patient. As part of its government sponsored Marijuana for Medical Purposes Regulations, Canadians can legally obtain medical marijuana from government regulated growers; however, only under the provision of a physician “prescription” that expires after one year. One barrier to the coverage of medical marijuana by insurance plans is that the Centers for Medicare and Medicaid Services (CMS) will not provide payment for products or services if a provider does not comply with federal law; hence, the lack of payment potential for medical marijuana. Furthermore, the Schedule I status of marijuana prohibits the assigning of a National Drug Code (NDC) to these substances, leading to the inability of Pharmacy Benefit Managers (PBMs) to process claims for this controversial treatment option.

**Optum®**

Our core philosophy centers on achieving better outcomes while promoting safe and effective treatment modalities. We work closely with our clients and industry stakeholders to help injured parties reach their maximum level of pain control and function. At the present, medical marijuana does not have the essential quality control measures to ensure safe prescribing and dispensing. While we remain respectful of the doctor-patient relationship, the ultimate decision of payment resides with the payer. Therefore, based on the best available scientific evidence, lack of essential quality control measures, an unchanged Schedule I classification and the absence of NDC needed for adjudication and processing, our position is that medical marijuana is neither a safe nor a reliable treatment option for the injured worker. Accordingly, it remains excluded from our Medication Plans and formularies. At this point in time,
any prescriptions received by Optum for medical marijuana are considered invalid as no FDA-approved/legal version of marijuana is currently available on the U.S. market. The Pharmacy and Therapeutic Committee, in conjunction with our Clinical Services department, continues to review drugs for coverage and will continue to do so in the future. This position has been carefully developed through an objective review of existing medical evidence, recommendations from national addiction agencies and the most current workers’ compensation industry guidelines. As discussion and research on this topic continues, we will continue to share our expertise in medication optimization and non-pharmacologic treatment options. For more information regarding medical marijuana, our position or our program, please contact your account manager or sales representative.

**Conclusion**

While workers’ compensation requests for approval of medical marijuana in the treatment of pain may continue in states where use has been legalized, presently, the use of marijuana for medicinal purposes remains inconsistent with federal law, and payment for its use is not covered by the Centers for Medicare and Medicaid Services. Although proponents of legalizing marijuana for medicinal purposes continue to cite potential benefits, particularly in the chronic pain population, there is a lack of substantial clinical data evaluating the safety and efficacy of this treatment strategy. For the time being, insurers are advised to carefully evaluate their position on the matter and draft appropriate policies regarding their decision on the coverage/status of marijuana for medicinal purposes. As with any medication that may have adverse effects, careful evaluation of the availability of safer, more effective treatment options should be considered.
References

About Optum for Workers’ Compensation
The workers’ comp division of Optum collaborates with our clients to deliver value beyond transactional savings while helping ensure injured workers receive safe and effective clinical care. Our innovative and comprehensive medical cost management programs include pharmacy, ancillary and managed care services from first report of injury to settlement.

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