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Medication-Assisted Treatment for Opiate Addiction

Frequently Asked Questions (FAQ's): Medication-Assisted Treatment for Opiate Addiction

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What medications are currently approved by the Food and Drug Administration (FDA) for the treatment of opiate dependence?

Three medications are currently approved by the FDA for the treatment of opiate dependence: methadone, naltrexone and buprenorphine. Opiate dependence involves addiction to opioid substances such as heroin and *prescription* narcotic pain killers.

Methadone is available as a generic drug and as a branded product under the names Methadose[®] and Dolophine[®]. Oral naltrexone to treat opiate dependence is available as both a generic drug and as a branded drug under the names of Revia[®] and Depade[®]. *Injectable naltrexone branded as Vivitrol[®] is available to treat alcohol dependence.* Buprenorphine to treat opioid dependence is available only as a branded drug under the names Suboxone[®] and Subutex[®].

What medications have been approved by the FDA for treatment of alcohol abuse?

The FDA has approved two anti-anxiety drugs, Valium (diazepam) and Librium (chlordiazepoxide), for treating alcohol withdrawal. Use of these drugs beyond the withdrawal phase is not advised for alcoholics because of the drugs' potential abuse and alcoholics' potential for dependence. Under certain circumstances, it may be appropriate to use lorazepam or oxazepam for withdrawal. Three drugs—disulfiram, naltrexone and acamprosate calcium—have been approved to treat alcohol abuse.

Disulfiram, available as a generic and also under the brand name Antabuse[®], has been on the market since 1948. It prevents alcohol use by causing an unpleasant, severe reaction—including facial flushing, throbbing headache, nausea, vomiting and increased blood pressure and heart rate—if the person taking it drinks even a small amount of alcohol.

Naltrexone, available as a generic drug and also known under the brand names ReVia[®] and Depade[®], was approved by the FDA in December 1994 to treat alcoholism. It acts on the brain to help prevent relapse and reduce alcohol cravings in those who drink. Injectable naltrexone, Vivitrol[®], is long-acting. It was approved by the FDA on April 13, 2006, for treating alcoholism. A long-lasting injectable can reduce the craving for alcohol and minimize alcoholic drop out. Administered intra-muscularly, the medication lasts up to 30 days.

Acamprosate calcium, sold under the brand name Campral[®], was approved by the FDA in 2004 to help alcoholics remain abstinent. Acamprosate reduces the physical and emotional discomfort (e.g., sweating, anxiety, sleep disturbances) many people feel after they stop drinking, making it easier for them to abstain after the immediate withdrawal period.

What other medications have been approved by the FDA for treatment of alcohol and substance dependence?

No other medications have yet been approved by the FDA to treat alcohol and substance abuse. However, the National Institutes of Health are supporting research into many other medications that may, in the future, be found to be effective. The FDA will approve other

medications to treat alcohol and substance dependence only after scientific research studies prove them to be clinically effective.

Are buprenorphine and methadone both effective in the treatment of opiate dependence?

Scientific research shows that both medications are effective for treatment of opiate dependence when combined with counseling and other psycho-social supports.¹ Because of the pharmacologic differences between these two medications and the regulations that affect how they are dispensed, one medication may be more appropriate for certain patients than the other. Under current regulations, for example female patients who are pregnant generally receive methadone in opiate treatment programs. Although buprenorphine is not approved to treat opiate dependence in pregnant women, it can be prescribed if the physician believes the benefits outweigh the risks. The National Institute on Drug Abuse is funding a multi-center trial to compare buprenorphine and methadone treatment for pregnant, opiate-addicted women. If results are equally positive for both medications, data from this trial will be shared with the FDA so both can be approved to treat opiate-addicted pregnant women.

Patients in rural areas, those without ready access to transportation, or those who have employment or child care responsibilities may prefer treatment with buprenorphine because it can be prescribed in a local physician's office and the medication can be obtained in local pharmacies. This is more convenient for some than a daily trip to a methadone clinic for required observed dosing.

Is using medications to treat opiate dependence simply replacing one addiction with another?

As used in opioid dependence treatment, buprenorphine and methadone are not heroin substitutes, nor is naltrexone. Their pharmacologic effects differ substantially those of heroin. Buprenorphine and methadone reduce cravings and prevent withdrawal, making the person more amenable to receiving related help for his or her addiction.

Although buprenorphine and methadone are pharmacologically different from one another, both are long-acting medications. Both are recognized by the FDA and the National Institute of Drug Abuse as effective medications to treat opioid dependence when combined with appropriate counseling and psycho-social treatment.

Methadone for treatment of opiate dependence is available only in Federally regulated and certified programs approved by the Center for Substance Abuse Treatment. Buprenorphine can be prescribed only by physicians who complete appropriate training and receive a waiver from the Center for Substance Abuse Treatment and a DEA X number from the DEA.

What is an agonist and how does it work to treat opiate dependence?

An agonist binds to a specific receptor in the brain and triggers a brain cell response. It mimics the action of another substance such as heroin that binds to the same receptor. A full agonist has an affinity for and binds with a receptor to activate it, displacing the other

medication at that receptor. Methadone is a full agonist that acts on the brain's opioid receptors to fill those receptors and block the effects of other opiates.

A partial agonist also binds with and activates a given receptor, but is only partially effective at the receptor. Buprenorphine is a partial agonist but it also has antagonist actions to opioids. Partial agonists limit the potential for overdose, increasing their safety and may make withdrawal from opiates easier for patients.

Although opiate agonists are useful in treating opiate dependence when combined with appropriate counseling and psycho-social treatment, they also can be abused.

What is an antagonist and how does it work to treat opioid dependence?

An antagonist is a drug that blocks opioids from acting on the brain. Naltrexone, an opioid receptor antagonist, is used to treat both opioid and alcohol dependence. Because naltrexone temporarily blocks the effects of opioids but does not affect craving, its use to treat opioid dependence is limited. Buprenorphine also has some antagonist actions in the brain.

How many states provide public funding through Medicaid to treat opioid abuse and dependence using methadone?

Treatment using methadone is provided in public opioid treatment programs that, according to the Center for Substance Abuse Treatment, exist in all but five states—Idaho, Montana, North Dakota, South Dakota and Wyoming. According to SAMHSA's information, 28 of the states that have opioid treatment programs offer funding for through their Medicaid programs.² (Note: These 28 states include many of the largest states that have the most Medicaid recipients. This information currently is being updated; updates will be available on this website.)

What sources of federal funding, other than Medicaid, are commonly used to support medication-assisted treatment of opioid abuse and dependence?

Some additional potential sources of federal funding that are available and may be used to support medication-assisted treatment of opiate abuse and dependence are:

- Veterans Administration
- Substance Abuse Prevention and Treatment Block Grant (SAPTBG)
- Medicare
- Human Resources Services Administration (HRSA): Federally Qualified Health Centers
- AIDS Drug Assistance Programs (ADAP)
- Treatment Drug Courts and/or Access to Recovery Programs (ATR) funded by CSAT/SAMHSA

Limitations exist for these funding sources, however. Each has its own patient eligibility requirements and may limit the duration, scope or other aspects of services provided. For example, Medicare does not cover methadone maintenance. Use of methadone to treat

opiate dependence is covered by Medicare for only a limited time for withdrawal. Similarly, both the Veterans Administration and FQHCs have limited capacity in any given geographic area.

The Substance Abuse Prevention and Treatment Block Grant, which is provided to every state, supports a wide range of substance abuse treatment services. States can use the grants to support medication-assisted treatment of opiate abuse and dependence if they wish. Slightly more than half the states use Medicaid funding for this purpose.

A variety of other federal sources also is available, but they may be highly targeted to small subsets of the population or fund demonstration or discretionary projects for a limited period of time. An example of the latter is a buprenorphine initiative developed by the HIV/AIDS Bureau of the Health Resources and Services Administration. It is designed to determine the effectiveness of integrating treatment of opioid abuse with buprenorphine in HIV primary care settings.³ This initiative, which began in September 2004, is comprised of 10 demonstration sites coordinated by a technical assistance/evaluation center.

What is a formulary or a preferred drug list?

A formulary is a list of prescription drugs that has been approved by a state or health plan to be dispensed without prior authorization from state or other pharmacy experts. Formularies are used to control the cost and manage the use of prescription drugs. Some are more restrictive than others. “Open” formularies provide coverage for both listed and non-listed drugs, although physicians are encouraged to prescribe drugs included on the list. “Closed” formularies generally provide coverage only for drugs included on the list. Under a tiered cost-sharing approach, generic and “preferred” or listed drugs require lower co-payments than brand name and non-preferred drugs. Formulary processes typically include procedures to access non-formulary drugs that are medically necessary and procedures to allow patients to appeal coverage decisions.⁴

Is access to a treatment of opiate dependence assured if the appropriate treatment medication is on a formulary?

No, it is not assured, but it helps those covered by the public medical plan such as Medicaid. A drug that is placed on a formulary may have limitations or restrictions such as prior authorization. Even if a medication is on a formulary, patients may have difficulty obtaining it if it is not on the highest tier. A payer such as Medicaid may limit the number of prescriptions that a patient may obtain during a given time or limit the length of time for which a particular medication may be reimbursed and/or require frequent reauthorizations. However, medications to treat substance dependence are most effective when taken in concert with counseling and recovery support services that also need to be available. Placing a medication for substance dependence treatment on a formulary is not sufficient to provide access to treatment if benefits such as physician visits, laboratory services and counseling are not covered and available. (NCSL and Avisa are surveying states about the Medicaid formulary status of and limitations on medications to treat opiate dependence.)

How does regulation of medications used to treat opiate dependence differ from regulation of other medications in general or when these special medications are used to treat pain?

A unique regulatory regime applies to methadone and buprenorphine when they are used to treat opiate dependence.

Methadone

Methadone is used to treat pain and to treat opiate dependence. Physicians may prescribe methadone for pain as they may prescribe any other opiate medication. When methadone is used to treat opiate dependence, however, it must be dispensed by a federally certified opiate treatment program. These programs are certified by SAMHSA and are state-licensed. Oversight of medications used to treat opiate dependence involves states, DHHS/SAMHSA and the U.S. Department of Justice Drug Enforcement Administration.

Buprenorphine

Buprenorphine is used to treat post-surgical pain and opiate dependence. Physicians may prescribe buprenorphine to treat post-surgical pain as they prescribe any other opiate pain medication. The only FDA-approved buprenorphine formulations to treat opiate dependence are Subutex[®] and Suboxone[®]. Subutex[®] is most commonly used for detoxification only in the U.S. Suboxone[®], used to treat opiate dependence in the United States, is a sublingual tablet that contains buprenorphine and naloxone, an opiate antagonist, in order to prevent diversion.

To prescribe Subutex[®] and Suboxone[®], a physician must complete formal training and receive a special waiver, which is overseen by SAMHSA.⁵

Notes

1. NIDA: “Methadone and buprenorphine, for example, are effective medications for the treatment of opiate addiction. Acting on the same targets in the brain as heroin and morphine, these medications block the drug’s effects, suppress withdrawal symptoms and relieve craving for the drug. This helps patients to disengage from drug-seeking and related criminal behavior and be more receptive to behavioral treatments.”

<http://www.drugabuse.gov/Infofacts/treatmeth.html>

2. http://mentalhealth.samhsa.gov/Publications/allpubs/State_Med/StateProfiles.pdf

3. http://hab.hrsa.gov/special/bup_index.htm

4. National Health Policy Forum

http://nhpf.ags.com/pdfs_basics/Basics_Formulary.pdf

5. For more information about the SAMHSA waiver program, see the following:

http://buprenorphine.samhsa.gov/waiver_qualifications.html