

Department of Human Services Division of Medical Assistance & Health Services New Jersey Drug Utilization Review Board BULLETIN

Volume No 01 No. 04 May 2009

TO: Physicians, Advanced Practice Nurses, Clinics, Federally Qualified

Health Centers- For Action

Providers of Pharmaceutical Services, Health Maintenance

Organizations – For Information Only

SUBJECT: Clinical News from the New Jersey Drug Utilization Review

Board (DURB)

PURPOSE: To provide practitioners useful clinical information that may be

helpful to the prescribing of prescription drugs

BACKGROUND: The DURB serves as an advisory board to the New Jersey Department of Human Services and the New Jersey Department of Health and Senior Services. The Board's responsibilities include recommending clinical standards based, in part, on the evaluation of prescription drug use by participants in the State's prescription drug programs. The Board is also responsible for disseminating information that the Board has determined would encourage appropriate drug utilization.

ACTION: Attached is a discussion regarding an Update on Suboxone®/
Subutex®Prescribing. For more information pertaining to this topic please see Bulletin Volume 01 No. 05 by visiting http://www.nj.gov/humanservices/dmahs/durb.html. The Board welcomes your comments regarding this bulletin. Send comments to www.state.nj.us/humanservices/dmahs/durb.html. The Subject should read, "DURB Comments."

RETAIN THIS NEWSLETTER FOR FUTURE REFERENCE



State of New Jersey Department of Human Services Division of Medical Assistance & Health Services New Jersey Drug Utilization Review Board

Buprenorphine/Naloxone for Opioid Dependence

This bulletin is intended to encourage appropriate utilization of Suboxone® and Subutex® treatment modalities

Opioid dependence/addiction is a major public health problem. More people die in New Jersey every year from unintentional drug overdoses than from automobile accidents. Many of these individuals are addicted to either illicit or prescription opioids. Treatment for this addiction was until recently limited to methadone maintenance and involved detoxification and then ongoing daily attendance at a methadone clinic. While the support and social services at such clinics are important to some patients, there has been a need for more resources that are also more convenient, without the social stigma, to decrease barriers to seeking treatment.

In 2002, the FDA approved Suboxone® (buprenorphine + Naloxone) and Subutex® (buprenorphine) for treatment of opioid dependence in the independent medical office setting. Unlike methadone, these may be prescribed in the office setting and filled at a retail pharmacy.

The physician must complete an 8-hour training program, register and receive a special license from the Drug Enforcement Administration. (See below for more information.) This requirement is not burdensome and should make it possible for many more patients to receive treatment while continuing with their work and lives in the community.

DRUG INFORMATION:

Buprenorphine is a partial opioid agonist, which has been used for pain management for years. It is similar to other opioids such as morphine, codeine, and heroin and therefore can produce typical opioid agonist effects and side effects. However, it produces less euphoric effects and therefore may be easier to stop taking. Its effects are less than those of full agonists. Naloxone is an opioid antagonist. Suboxone® combines naloxone and buprenorphine in a

tablet to produce smooth withdrawal and maintenance for as long as necessary. If it is injected contrary to recommendations, Naloxone will block the effects of buprenorphine and lead to withdrawal symptoms in a person with an opioid addiction.

Dosage:

Induction doses (usually given at the physician's office) should begin with 2 or 4 mg on day 1, which can be repeated q 2 to 4 hours if withdrawal symptoms subside and then reappear (max. 8mg on day 1), and titrated in 2 to 4 mg increments to 12 to 16 mg on day 2. Most patients can be stabilized on 8 to 32 mg/day. Doses higher than 32 mg may cause opioid-withdrawal symptoms. Alternate day and three-times-a-week (TIW) schedules have also been used.

Side Effects:

The most common adverse effects are related to its opioid qualities and include sedation, nausea, itching and constipation.

For more information on dosing and other prescribing issues, call 1-877-SUBOXONE (1-877-792-6966), or visit the website at:

www.suboxone.com

Training and Certification:

There are many resources available.

Phone: 1-888-DOC-OPT-IN (888-362-6784)

Websites:

www.buprenorphine.samhsa.gov

www.DocOptIn .com

www.asam.org/conf/BupMentoring/PCSS.htm

www.aaap.org/contact.htm

www.aoaam.org

www.psych.org

www.asam.org

Regulatory Requirements:

To receive a waiver to practice opioid addiction therapy using Suboxone® or Subutex®, a physician must notify the Center for Substance Abuse Treatment (CSAT), a component of the Substance Abuse and Mental Health Services Administration (SAMHSA) of his/her intent to begin dispensing or prescribing this treatment.

For more information on regulatory requirements, contact SAMHSA at:

1-877-SAMHSA-7 (1-877-726-4727) or visit their website at:

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

References:

- 1. About Buprenorphine Therapy. U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration. Accessed online at: http://buprenorphine.samhsa.gov/about.html
- 2. Buprenorphine: An Alternative to Methadone. The Medical Letter, February 17, 2003; 45 (W1150A)