Suboxone

Can Suboxone Be Used for Pain Management?

Yes, Suboxone may be used for pain management. If the physician writes a prescription for Suboxone for pain management, the prescription may be called in to the pharmacy. Suboxone prescriptions for addiction management may not be called or faxed into the pharmacy, without the physician first obtaining a HIPAA release form from the patient.

BUTRANS should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.

BUTRANS is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Limitations of Use:

- Because of the risks of addiction, abuse and misuse with opioids, even at recommended doses, and because of the greater risk of overdose and death with extended-release opioid formulations, reserve
- BUTRANS for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- BUTRANS is not indicated as an as-needed (prn) analgesic

Suboxone

What Are the Guidelines for Use of Suboxone for Treatment of Addiction?

NDA 20-732 NDA 20-733 Page 43 by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose.

Information for Pharmacists

SUBOXONE® (buprenorphine HCl/naloxone HCl dihydrate, sublingual tablet)

and SUBUTEX® (buprenorphine HCl, sublingual tablet)

What are SUBOXONE and SUBUTEX?

SUBOXONE and SUBUTEX are sublingual tablets indicated for the treatment of opioid dependence. SUBOXONE contains buprenorphine (a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor) and naloxone (an antagonist at the mu-opioid receptor). SUBUTEX contains buprenorphine only.

Why is it important for all pharmacists to learn about SUBOXONE and SUBUTEX?

For the first time, pharmacists will play a role in the delivery of opiate addiction treatment. SUBOXONE and SUBUTEX are the first medications approved for office-based treatment of opioid dependence under the Drug Addiction Treatment Act of 2000 (DATA). Prior to the passage of this law, it was illegal for a doctor to prescribe narcotic drugs for the treatment of narcotic dependence. Opioid dependence treatment of this type could only be provided at specially registered clinics. Under the new law, only opiate addiction treatment drugs under Schedule II are confined to use in the clinic setting. Less tightly controlled drugs (Schedules III-V) may be prescribed for opiate NDA 20-732 NDA 20-733 Page 44

addiction treatment by specially qualified doctors who treat patients in their private offices.

: **Why are there two formulations?**

SUBOXONE is the preferred medication for maintenance treatment due to the presence of naloxone in the formulation, which is intended to deter intravenous abuse by persons dependent on other opiates. SUBUTEX, which does not contain naloxone, may be better tolerated by patients in the first several days of treatment and is generally preferred for induction. “Induction” refers to the initial period of treatment, during which time the patient should receive medication under the doctor’s supervision in the office. Patients or their family members may need to come and pick up induction doses each day for the first several days of treatment (or you may be asked to arrange delivery to the doctor’s office, if your pharmacy provides this service). Therefore, while you may see prescriptions for small amounts of SUBUTEX presented for induction doses, you should expect the majority of prescriptions to be for SUBOXONE.

SUBOXONE and SUBUTEX are controlled as Schedule III narcotics under the Controlled Substances Act.

How are they supplied?

SUBOXONE is supplied as hexagonal orange tablets in 2 dosage strengths:

2 mg buprenorphine + 0.5 mg naloxone embossed with a sword logo at the midline and N2 on the reverse side

and 8 mg buprenorphine + 2 mg naloxone embossed with a sword logo at the midline and N8 on the reverse side, , NDA 20-732 NDA 20-733 Page 45 SUBUTEX is supplied as oval white tablets in in 2 dosage strengths: 2mg buprenorphine embossed with a sword logo at the midline and B2 on the reverse side and 8mg buprenorphine embossed with a sword logo at the midline and B8 on the reverse side **I’ve heard that buprenorphine is safer than methadone. Can these drugs be dangerous?** Significant respiratory depression has been associated with

buprenorphine, particularly when administered intravenously. A number of deaths have occurred when addicts have intravenously misused buprenorphine, usually with benzodiazepines concomitantly. Deaths have also been reported in association with concomitant administration of buprenorphine and other depressants such as alcohol or other opioids **Do SUBOXONE and SUBUTEX cause dependence?** Chronic administration of SUBOXONE or SUBUTEX produces dependence of the opiate type, characterized by withdrawal upon abrupt discontinuation or rapid taper. The withdrawal syndrome is milder than seen with full agonists, and may be delayed in onset. Because it contains naloxone, SUBOXONE is highly likely to produce marked and intense withdrawal symptoms if misused parenterally by individuals dependent on opioid agonists such as heroin, morphine, or methadone. Sublingually, SUBOXONE may cause opioid withdrawal symptoms in such persons if administered before the agonist effects of the opioid have subsided. **Be sure to read the full Prescribing Information for complete Warnings & Precautions.** NDA 20-732 NDA 20-733 Page 46

What other information should I relay to patients?

It's important that you make sure patients understand their physicians' instructions, and that you answer any questions they may have.

When counseling patients, be sure to discuss any relevant precautions as listed in the Prescribing Information, including but not limited to the following:

- Patients should inform their family members that, in the event of emergency, the treating physician or emergency room staff should be informed that the patient is physically dependent on opioids and that the patient is being treated with SUBOXONE or SUBUTEX

- Patients should be cautioned that a serious overdose may occur if benzodiazepines, sedatives, tranquilizers, antidepressants, or alcohol are taken at the same time as SUBOXONE or SUBUTEX

- Patients should be cautioned that SUBOXONE or SUBUTEX may impair the mental or physical abilities required for the performance of potentially dangerous tasks such as driving a car or operating machinery. Patients should be cautioned not to drive or operate complex machinery until they know how SUBOXONE or SUBUTEX affects their ability to function in these circumstances, such as driving a car.

- Patients should consult their physician if other prescription medications are currently being used or are prescribed for future use

What are the possible side effects of SUBOXONE and SUBUTEX?

The most common adverse events reported in clinical trials with SUBOXONE and SUBUTEX were headache, withdrawal syndrome, pain, nausea, insomnia, sweating, abdominal pain, back pain, constipation, infection, asthenia, rhinitis, anxiety, and depression.

What is the role of the pharmacist in ensuring safe use of SUBOXONE and SUBUTEX?

As a pharmacist, you will play an important role in ensuring that SUBOXONE and SUBUTEX are used safely and appropriately. Each time you fill a prescription for SUBOXONE or SUBUTEX, make sure to:

- Verify that the prescriptions you receive are from physicians who are in compliance with the provisions of the DATA (see below).

- Remind patients who are picking up induction doses to return as directed to the doctor's office so that they can be supervised while taking the medication.

- Be vigilant in detecting fraudulent prescriptions or simultaneous prescriptions for the same patient from multiple suppliers.

Who is qualified to prescribe SUBOXONE and SUBUTEX?

The DATA limits office-based use of SUBOXONE and SUBUTEX to physicians who meet special training criteria and can provide appropriate services. To be qualified, physicians must:

Meet one or more of the following training requirements

- Hold a subspecialty board certification in addiction psychiatry from the American Board of medical Specialties

- Hold a subspecialty board certification in Addiction Medicine from the American Osteopathic Association

- Hold an addiction certification from the American Society of Addiction Medicine

- Have completed not less than 8 hours of authorized training on the treatment or management of opioid-dependent patients. This training may include classroom situations, seminars at professional society meetings, electronic communications, or other media. The American Society of Addiction Medicine, The American Academy of Addiction Psychiatry, the

American Medical Association, the American Osteopathic Association, and the American Psychiatric Association are all authorized to provide this training.

- AND meet both of the following criteria:

- Have the capacity to provide or to refer patients for necessary ancillary services, such as psychosocial therapy.

- Agree to treat no more than 30 patients at any one time in their individual or group practice

How can I be sure a physician is qualified to prescribe SUBOXONE and SUBUTEX?

Physicians who meet the qualification criteria listed in the previous section must also notify the Secretary of Health & Human Services of their intent to prescribe SUBOXONE and SUBUTEX before doing so. Once all relevant criteria are verified, DEA will issue the physician a unique identification number indicating that he or she is a qualifying physician under the DATA. NDA 20-732 NDA 20-733 Page 49

The Center for Substance Abuse Treatment (CSAT, a component of the Substance Abuse and Mental Health Services Administration) will send a letter informing the physician of the new DEA identification number. The physicians will subsequently receive a revised DEA registration certificate (showing both numbers).

Pharmacists who seek information to verify whether or not physicians have valid waivers may contact 1-866-BUP-CSAT, or by email at info@buprenorphine.samhsa.gov

What if I get a prescription from a doctor who does not have a special DEA identification number?

Call that physician for clarification that the physician has made the appropriate notification to DHHS. DEA is developing regulations that will require this number along with the physician's existing DEA registration number to be included on all prescriptions issued for the treatment of opioid dependence; therefore physicians are being strongly urged to include this number on prescriptions.

Most physicians will make arrangements to obtain the identification number before prescribing SUBOXONE or SUBUTEX, but in rare cases a physician may need to write a prescription before the number has been issued. This is allowed under the DATA provided the physician has notified the Department of Health and Human Services of his/her intention to begin treating a patient right away; the notification form includes a check box for this situation.

Are there confidentiality issues I should be aware of related to substance abuse treatment?

There are special federal regulations concerning the confidentiality of substance abuse treatment records (42 CFR Part 2) and the privacy of health records (HIPAA)which may come into play in your interactions with physicians to verify prescriptions for SUBOXONE and SUBUTEX. To ensure that physicians will be able to communicate NDA 20-732 NDA 20-733 Page 50

with you to confirm the validity of a SUBOXONE or SUBUTEX prescription, it is recommended that the physician have the patient sign a release of information at the time of the office visit. A sample consent form with all the elements required under 42 CFR Part 2 is included with this booklet as an attachment. It is particularly important to obtain the patient's consent if the physician elects to phone or FAX in prescriptions, as this constitutes disclosure of the patient's treatment. When the prescription is directly transmitted by the physician, there are also prohibitions on the further redisclosure of patient identifying information by the pharmacist. 42CFR Part 2 does not apply when it is the patient who delivers the presciption to the pharmacist, without direct communication from the physician to the pharmacist.

To learn more about these regulations, visit the SAMHSA website www.hipaa.samhsa.gov, or call 1-866-BUP-CSAT for information.

Again, Pharmacists who seek information to verify whether or not physicians have valid waivers may contact 1-866-BUP-CSAT, or by email at info@buprenorphine.samhsa.gov

How will physicians obtain supplies of medication for induction?

Because induction doses of SUBOXONE and SUBUTEX should be given in the physician's office, many physicians will maintain a supply of each medication in their office. Most physicians will get this supply through their normal supplier or the manufacturer. Some physicians, however, will write prescriptions for individual patients' induction doses at the time of the patient appointment. The prescribing physician may call or fax ahead to your pharmacy to request delivery (if you provide this service), or to ensure the medication will be ready in advance of the patient's arrival. (Recall that the patient is likely to be in mild withdrawal while awaiting the prescription.) Some physicians may send a patient's family member to the pharmacy to pick up the induction dose. NDA 20-732 NDA 20-733 Page 51

What should I do when a patient presents a prescription for an induction dose?

Physicians who choose not to maintain supplies of SUBOXONE or SUBUTEX in their offices may give their patients a prescription for their induction doses with instructions to return to the office for supervision while the dose is administered. Fill the prescription as you normally would, then make sure the patient understands that he or she must return to the doctor's office to take the medication. It may take several days of supervised administration to complete

the induction process, therefore, some patients may be visiting your pharmacy repeatedly at the beginning of treatment.

Where state laws allow, patients may be provided with a coupon that covers the cost of the first day's dose. The coupon presented to you by the patient can be submitted to reimburse the cost of the medication.

Are there any special storage, record-keeping, or other requirements associated with SUBOXONE and SUBUTEX?

As Schedule III controlled substances, SUBOXONE and SUBUTEX are subject to certain federal regulations covering areas such as record-keeping, inventory, proper dispensing and disposal. These are explained in the Drug Enforcement Administration's Pharmacist's Manual, which can be found at

www.deadiversion.usdoj.gov/pubs/manuals/pharm2/index.htm.

Many states have their own, additional requirements for pharmacists dispensing controlled substances. Be sure to check with the appropriate authority in your state. For more information, visit the website of the National Association of Boards of Pharmacy at www.nabp.org for links to individual state boards of pharmacy. NDA 20-732 NDA 20-733 Page 52

In addition, since drug addiction is a sensitive topic, you should make sure you have access to a private area in which to counsel patients about SUBOXONE and SUBUTEX therapy. When speaking with these patients, it is important to keep in mind that addicts in withdrawal may be irritable and short on patience.

What else can I do to help safeguard against diversion?

According to federal law, pharmacists and prescribers jointly share legal responsibility for the legitimacy of a prescription. Communication between you and the prescriber is vital to ensure the validity of each prescription you're asked to fill.

However, even if you determine that an individual prescription is legal, you should still be aware of other means by which addicts may attempt to divert their prescriptions. For example, an opioid user may present to 2 or more qualified prescribers, and therefore receive multiple prescriptions for SUBOXONE or SUBUTEX. If a patient brings you more than 1 prescription covering the same therapeutic period, you have a legal duty to recognize that they are probably not for therapeutic use. You should refuse to fill the second prescription, and notify both prescribing physicians.

In addition, you should be aware that the DATA allows each physician to treat no more than 30 patients with buprenorphine at any one time. Obviously, as patients enter and leave treatment, more than 30 patients will be cared for by a particular physician over the course of time. However, if you notice an extraordinary number of new prescriptions from a single physician, you may wish to check with the prescriber to determine whether the prescriptions might be fraudulent.

Where can I get more information on treating opioid addiction with SUBOXONE and SUBUTEX? NDA 20-732 NDA 20-733 Page 53

- Refer to the package insert for full information on the adverse events seen during the clinical trials using buprenorphine for opiate addiction treatment.

- Clinical guidelines for buprenorphine treatment and general information on the treatment of addiction is available through numerous sources such as the following: Substance Abuse and Mental Health Services (SAMHSA) Center for Substance Abuse Treatment (CSAT) Web site at www.dpt.samhsa.gov American Society of Addiction Medicine Web site at **www.asam.org/** and the American Academy of Addiction Psychiatry website at

www.aaap.org/

For more information, call our toll-free help line at 1-877-SUBOXONE (1-877-782-6966) or visit our Web site at www.suboxone.com.

Please see enclosed full Prescribing Information

Attachment to Pharmacist Brochure: SAMPLE 42 CFR Part 2.31 Consent Form

1.I (name of patient) _____{time} Authorize:

2. Dr._____

3. To disclose: (kind and amount of information to be disclosed) Any information needed to confirm the validity of my prescription and for submission for payment for the prescription.

4. To: (name or title of the person or organization to which disclosure is to be made) The dispensing pharmacy to whom I present my prescription or to whom my prescription is called/sent/faxed, as well as to third party payors.

5. For (purpose of the disclosure) Assuring the pharmacy of the validity of the prescription, so it can be legally dispensed, and for payment purposes.

6. Date (on which this consent is signed)_____

7. Signature of patient _____

8. Signature of parent or guardian (where required)