ILLINOIS DEPARTMENT OF Healthcare and Family Services

Suboxone® (buprenorphine/naloxone) tablets, films and buprenorphine tablets Prior Authorization Criteria

All prescriptions for Suboxone (buprenophine/naloxone) tablets, films or buprenorphine tablets (previously available as Subutex®) require prior authorization. To ensure optimal treatment results, prescribers must use a multi-modal opiate addiction treatment approach, which includes induction, stabilization, maintenance, and a physician supervised program including psychosocial support and counseling. [1-3]

The Illinois Department of Human Services (DHS), Division of Alcoholism and Substance Abuse (DASA), provides intervention, treatment, rehabilitation, and other services to those who misuse alcohol or other drugs. Prescribers are encouraged to refer patients to a DASA provider for counseling or other services. A complete listing of DASA providers is available on the DHS website at http://www.dhs.state.il.us/page.aspx?item=29725.

The goal of the Suboxone/buprenorphine prior authorization requirement is to ensure that HFS is covering Suboxone/buprenorphine for patients who are committed to ending their substance abuse and to prevent the medication from being misused, abused, or diverted. In addition, the prior authorization requirements seek to ensure that the medication is used in conjunction with substance abuse treatment counseling services, so that patients may work toward long-term recovery from their substance abuse problems.

INITIAL APPPROVAL: Suboxone tablets/films and buprenorphine tablets

In addition to the following criteria, prescribers should plan for how short- and long-term pain will be managed with non-opiod analgesics if patients require treatment for pain while receiving Suboxone/buprenorphine therapy and how concurrent use of alcohol will be addressed.

1. Patient must have a diagnosis of opiate addiction.
2. Prescriber must be actively enrolled in Illinois Medicaid.
3. Prescriber has met the qualifications for a waiver under the Drug Addiction Treatment Act of 2000 (DATA) and has an X-DEA number.
4. Prescriber must provide a treatment plan, signed by the prescriber and patient, which contains all of the following elements:
    a. Anticipated dosing plan for induction, stabilization, and maintenance phases;
    b. Plan for dose tapering;
    c. Plan for psychosocial counseling, including the name of the psychosocial program(s) to which the patient has been referred;
    d. Plan for follow up with the prescriber, i.e., frequency of office visits, etc.
    e. Description of schedule by which patient will obtain refill prescriptions, i.e., on a bi-weekly/monthly basis, etc.
    f. Informed consent regarding avoidance of combination use with opioids, benzodiazepines, sedative/hypnotics, stimulants, carisoprodol, tramadol, or alcohol;

g. Statement that the patient will only obtain Suboxone/buprenorphine prescriptions from the requesting prescriber, and will use the same pharmacy to fill their Suboxone/buprenorphine prescriptions and prescriptions for other pain medications, when necessary.
h. Urine drug screen results.

5. Initial approval will be limited to a 2-month period, to allow HFS to ensure that the patient is adherent to treatment and not continuing to abuse or misuse opioids or other abusable drugs. Quantity will be limited to 62 tablets/films per month (16 mg buprenorphine/day). For patients who require initial doses higher than this (maximum buprenorphine dose = 24 mg/day), prescriber may request 62 tablets/films for a 20 day supply until patient can be tapered down to a maximum buprenorphine dose of 16 mg/day.

Buprenorphine tablets - Additional criteria for patients who meet the criteria for Suboxone AND have one of the following indications.

1. Patient must be pregnant, breastfeeding, or have a documented allergy to naloxone.
2. Naloxone allergy: Physician must supply medical documentation of naloxone allergy (e.g. rash, hive, pruritis, bronchospasm, angioedema, anaphylactic shock). Symptoms of withdrawal induced by taking opioids and Suboxone in combination are not considered allergies.
3. Initial approval will be limited to a 2-month period.

RENEWALS: Suboxone tablets/films and buprenorphine tablets

1. Renewal requests must include:

   a. Illinois Prescription Drug Monitoring Program (PMP) Review Results: Prescriber must review the PMP database to ensure patient is not concurrently filling opioids, benzodiazepines, tramadol, carisoprodol, sedative/hypnotics, or stimulants. Justification for use of any of these medications in combination with Suboxone/buprenorphine must be provided along with a statement from the prescriber that this combination of medications is safe for use in the patient.
   b. Documentation demonstrating that the patient is participating in counseling programs, including name and location of program or counselor, and attendance records with dates and/or clinic notes.
   c. Urine screening results: Patient must have a negative drug screen for opiates, benzodiazepines, cocaine, cannabinoids, amphetamine, methamphetamine, and a positive result for buprenorphine. If patient has a positive drug screen for any non-prescribed medications or a negative result for buprenorphine, the patient should be re-assessed by the prescriber and justification provided to remain in the program.
   d. A revised plan for dose maintenance and tapering, if the initial plan for dosing is not being followed.
   e. Dates of inpatient detoxification admissions and drug/alcohol related ER visits since initial approval, including diagnosis/clinic notes.

2. Request will be denied if the patient has filled an opioid, benzodiazepine, sedative/hypnotic, tramadol, stimulant, or carisoprodol prescription during the most recent Suboxone/buprenorphine prior approval period or is not adhering to the prescribed treatment plan, counseling program, or monitoring requirements. Exceptions can be made in cases where a prescriber provides compelling justification for continued treatment with Suboxone/buprenorphine.
3. Renewals will be limited to two 3-month and one 4-month approval periods.
4. Early refills will not be allowed.
5. For pregnant women, buprenorphine tablet renewals will be allowed throughout the pregnancy, and, if applicable, the breastfeeding period.
6. Duration of therapy will be restricted to a maximum of **12 months in a lifetime**.

**These criteria are used to guide clinical decisions by the reviewing pharmacists. Prior approval determinations are made on a case-by-case basis. Compelling circumstances justified by the prescriber will be taken into consideration.

References:

1.Wesson DR, Smith DE. Buprenorphine in the treatment of opiate dependence. *J Psychoacttive Drugs*. 2010;42(2):161-175.

2. Center for Substance Abuse Treatment. *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*. Treatment Improvement Protocol (TIP) Series 40. DHHS Publication No. (SMA) 04-3939. Rockville MD: Substance Abuse and Mental Health Services Administration, 2001. http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf. Accessed October 1, 2012.

3. Suboxone® Sublingual Film [package insert]. Richmond, VA:Reckitt Benckiser Pharmaceuticals, Richmond VA. August 2012. http://www.suboxone.com/pdfs/SuboxonePI.pdf. Accessed October 29, 2012.