Medical Coverage Policy

Treatment of Opioid Dependence

☐ Device/Equipment ☒ Drug ☐ Medical ☐ Surgery ☐ Test ☐ Other

Effective Date:	07/05/2011	Policy Last Updated:	6/3/2008

☐ **Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.**

☒ **Prospective review is not required.**

Note: This policy addresses the use of buprenorphine as a maintenance treatment of opiate addiction and not the use of rapid withdrawal regimens.

Description:
The Food and Drug Administration (FDA) has approved two forms of buprenorphine, Subutex or Buprenex (buprenorphine hydrochloride) and Suboxone (buprenorphine hydrochloride and naloxone hydrochloride in a 4:1 ratio), for the treatment of opiate dependence. These drugs treat opiate addiction by preventing symptoms of withdrawal from heroin or other opiates and thereby reducing addiction behaviors. Federal law (DATA, the Drug Addiction Treatment Act) allows physicians to administer and/or prescribe buprenorphine for addiction treatment, including a maintenance phase whereby the drug may be utilized indefinitely. The law was intended to create greater access to opioid addiction treatment programs by facilitating the creation of a cohort of physician office treatment programs and an allowance for prescriptions for self-administration of the agents, when clinically appropriate. In contrast, methadone maintenance requires facility-based treatment and direct administration of the drug. The use of these agents in medication-assisted treatment of opioid addiction is regulated by federal and state statute.

Buprenorphine with naloxone (Suboxone) is used as an alternative to methadone for the maintenance treatment of opiate addiction. The drug is less rigidly controlled than methadone because it has a lower potential for abuse and is less dangerous in an overdose. The intention of adding naloxone to the formulation is to deter misuse. Buprenorphine is pharmacologically related to morphine and is a partial opioid agonist: It has the same effect on mu-opiod receptors in the brain as does heroin or other opiate drugs, but it has a ceiling affect whereby higher doses do not result in higher effects. Buprenorphine, when used correctly, reduces or eliminates withdrawal symptoms associated with opioid dependence but does produce the euphoria and sedation caused by heroin or other opiates. However, warnings exist that both formulations have the potential for abuse and produces dependence of the opioid type. Also, buprenorphine has been associated with significant respiratory depression, and several deaths have occurred when addicts intravenously misused the drug, usually concomitantly with benzodiazepines (sedative/hypnotics) or other depressants such as alcohol and other opioids.

Treatment is conducted in phases as described below.

Induction:

Patients must be assessed for opioid dependence and appropriateness for buprenorphine therapy. Once judged appropriate, patients may start treatment with buprenorphine alone or buprenorphine with naloxone. As naloxone is an antagonist, withdrawal may be precipitated when it is used. Therefore, patients on higher doses of long-acting narcotics will typically be treated with buprenorphine alone or converted to short-acting drugs or first undergo reduction in doses. They may also experience significant withdrawal regardless of buprenorphine administration and require symptomatic therapies. Patients are instructed to discontinue their opioids and are scheduled to be seen in the office at a time when they would begin to experience withdrawal symptoms. The presence of these symptoms is assessed and if present, the buprenorphine is administered usually at a dose of 4 mg (2-8 mg). The patient is observed for relief of withdrawal signs and symptoms or adverse effects. Symptoms are typically relieved in 20-40 minutes. If controlled, the patient is usually observed longer and at approximately 2-4 hours given a second 4 mg dose. Rarely, some patients with high likelihood of breakthrough withdrawal are sent home with a third nighttime dose.

The patients are then seen daily to assess whether withdrawal is controlled. Doses are adjusted as needed until a stable dose is found. A dose of not greater than 16 mg is maintained for several days before dosage escalation to allow steady state equilibration. Usually the target daily dose is determined or the maximum daily dose is reached by three days and administration can be changed to once daily.

Stabilization:

The goal of the stabilization phase is to attempt to reach a daily maintenance dose within 1-2 weeks. Patients started on buprenorphine without naloxone are converted to the combined product. Doses greater than 32 mg are not generally needed. Patients are regularly assessed for adherence, use of illicit drugs, intoxication or withdrawal and satisfaction. A “Treatment Improvement Protocol” guidelines (TIP 40) recommend that initial and ongoing drug screening should be used to detect or confirm the use of recent use of drugs which could complicate patient management. Urine screening is the most commonly used testing method.

Maintenance Therapy:

Once stable, patients enter maintenance therapy, which may last indefinitely. It may be associated with gradual dose reductions (medical withdrawal) and eventual elimination of treatment, or there may be an indefinite continuance to avoid relapse of addiction.

Dosage and Administration of Suboxone:

Suboxone treatment is intended for use in adults and adolescents more than 16 years of age and is administered sublingually as a single daily dose. The recommended target dose is in the range of 12 to 16 mg/day. The pill is placed underneath the tongue until it has fully dissolved and typically will be absorbed within 10-20 minutes. As patients progress on therapy, the physician may write a prescription for a take-home supply of the medication.

Physician Qualifications:

The Drug Addiction Treatment Act (DATA) requires that before physicians begin prescribing buprenorphine they must notify the Secretary of Health and Human Services-specifically the Division of Pharmacologic Therapies (DPT) within the Center for Substance Abuse Treatment (CSAT)-of their intent to treat patients with this product. CSAT will in turn notify the Drug Enforcement Administration (DEA) if, and when, the provider is qualified as required by DATA. Only those physicians who have approval from the DEA are able to start

in-office treatment and provide prescriptions for ongoing medication. The CSAT maintains an active database to help individuals locate qualified doctors. Buprenorphine treatment must be combined with concurrent behavioral therapies and with the provision of needed social services by the primary treating physician. Therefore, qualified physicians must be able to provide or refer patients for these services. Only physicians may be qualified in accordance with DATA. Other professionals with prescriptive privileges by state law are not eligible to be qualified.

Drug Testing and Other Compliance Monitoring:

Periodic testing for use of other opiates or illicit substances or alcohol misuse is expected in the management. Usually urine screening is performed during initial phases of treatment and randomly eight times a year. In order to be sure patients are not diverting medication, they may be required to report at random intervals to the office with their pill supply to be sure it is consistent with the prescribed use (i.e., no pills are missing.) Physicians must maintain careful records of prescribed doses. (Dispensed doses require exact narcotic administration records). Blue Cross & Blue Shield of Rhode Island (BCBSRI) may report to the prescribing physician regarding the prescription payment history and assess whether the patient receiving buprenorphine is receiving other opiates. The use of opiates to control acute pain may be appropriate, but such use is very complex when used in conjunction with suboxone due to antagonist affects, tolerance, and risk of over-dosage. Therefore, patients concomitantly receiving opiates and buprenorphine would be unusual when the agents are used in a clinically appropriate manner. BCBSRI may also monitor physicians to be sure that they are qualified by CSAT and prescribing in conformance with the regulations.

NOTE TO THE PRESCRIBER:

- The prescriber is responsible to adhere to the SAMHSA regulations for addiction treatment under the provisions of the Drug Addiction Treatment Act of 2000 (DATA 2000).
- The prescriber is responsible for complying with all associated state and federal opioid treatment and maintenance protocols as they relate to physician qualifications, privacy and confidentiality of the patient, dispensing and prescribing of buprenorphine products, record keeping and coordinating treatment with addiction and psychiatric treatment programs.

Medical Criteria:

Office-based treatment of opioid dependence requires the following:

- Diagnosis of opioid dependence 304.00, 304.01, 304.02
- Member has been informed on safe and effective alternatives to treatment and has chosen this method of treatment and understands the potential risks and benefits, and is willing and able to follow the treatment plan.
- Not dependent on high doses of benzodiazepines or other central nervous system depressants including alcohol.
- No co-occurring mental health conditions that may undermine the ability to participate in treatment.
- History of relapse does not indicate the need for a higher level of care.
- History of poor response to well-conducted episodes of buprenorphine treatment.

Policy:

Treatment of opioid dependence using buprenorphines is covered when the criteria above it met.

The treating physician must hold one of the following:

- A subspecialty board certification in addiction psychiatry from the American Board of Psychiatry and Neurology; or
- An addiction certification from the American Society of Addiction Medicine (ASAM); or
- A subspecialty board certification in addiction medicine from the American Osteopathic Association (AOA);or
- Has completed more than 8 hours of training on the treatment and management of opioid dependent patients from the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, or the American Psychiatric Association;
  AND
- Registration number and unique identification number form the Drug Enforcement Agency (DEA).

Treatment of Opioid Dependence shall consist of the following:

- **Assessment and Treatment Planning**
  · 1 - 2 office visits.
  · CPT code 90801 (used for psychiatrist. E&M services i.e. 99213 will be used by internal medicine and other non-psychiatrist medical doctors. Psychiatrists may also use E&M codes to report treatment during the Assessment and Treatment Planning phase if an E&M is the most appropriate code to be filed for the services rendered).

- **Induction**
  · 1 - 2 hour office visits.
  · Average frequency and duration of 3 times/week for two weeks
  · CPT code 99205 or 99215

- **Stabilization**
  · 1 - 2 office visits/week.
  · Average frequency and duration of 6 times/month for two months.
  · CPT code = 90805 or 90862. May use 90807 when clinically indicated.

- **Maintenance**
  · 1 office visit/month.
  · CPT code = 90862.

Coverage:

Physician office visits for pharmacologic management are covered as a medical office visit service. Substance abuse or mental health services (based upon service code and diagnosis submitted) are covered as mental health or substance abuse services when provided by a mental health professional. Drug testing is covered as a laboratory service. Physician dispensed oral medication is not covered. (Patients may receive initial doses from the pharmacy if the prescribing physician determines this to be appropriate.)

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for applicable Pharmacy, Behavioral Health, Diagnostic Testing, and Physician Office Visits benefit/coverage. All applicable

coinsurances, copayments, deductibles, and benefit limits will apply to the specific service billed.

Reimbursement and Coding:

There are no specific CPT codes for buprenorphine therapy. Most reported services directly related to buprenorphine therapy will be Evaluation and Management services (99201-99205, 99211-99215) or Pharmacologic Management (90862) if rendered by a psychiatrist.

Initial assessments by psychiatrists may require behavioral health code (90801).

Induction visits may require prolonged face-to-face visits (99201-99205 or 99211-99215 and 99354-99355).
There is no code for use of the office during observation periods, only face-to-face time by the physician is used when reporting prolonged services codes. Therefore, time must be carefully documented. Prolonged services codes require documentation review.

BCBSRI does not cover medication management in a group. Group therapy services provided in conjunction with Suboxone treatment is a covered benefit when a professional eligible to be a BCBSRI-credentialed clinician is present at the group meeting.

Participating providers may not charge members for covered services except as permitted for copayment, coinsurance, deductibles, and benefit limits.

Evaluation and Management Codes:
99201-99205, 99211-99215

Prolonged Services
99354-99355

Diagnosis Codes:
304.00 Opioid type dependence, unspecified
304.01 Opioid type dependence, continuous
304.02 Opioid type dependence, episodic

Also known as:
Suboxone
Subutex
Buprenex
Opioid Treatment

Related topics:
NA

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advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice.