


MEDICAL POLICY STATEMENT		
Effective Date	Next Annual Review Date	Last Review / Revision Date
08/5/2011		08/5/2011
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CSMG Medical Policy Statements are derived from literature based and supported clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services are those health care services or supplies which are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative and are not provided mainly for the convenience of the member or provider.

A. SUBJECT

Suboxone / Subutex

B. BACKGROUND

Suboxone / Subutex are CIII controlled medications used to treat opioid dependency and addiction. Clinical studies have demonstrated success in withdrawing patients completely from short and long acting opioids. It has also been demonstrated that Suboxone is commonly abused by combined usage with opioids and other commonly abused drugs and by diversion to unintended users and for unintended purposes.

CareSource will manage the use of Suboxone / Subutex by its members through a prior authorization program that ensures appropriate indication for and utilization of the drug. Suboxone / Subutex treatment should be accompanied by an ongoing counseling and psychosocial programs, and periodic urine screening to ensure compliance with management protocols.

Because of the limited access to physicians prescribing Suboxone, authorization for treatment will be given only for members who have demonstrated need, are motivated to comply with an addiction management program that includes companion counseling, and who remain compliant with proper dosing and abstinence from other opioids. Authorization for maintenance treatment will be discontinued for members who are non-compliant with a defined treatment program or utilizing other opioids.

C. POLICY

CareSource will approve the use of Suboxone / Subutex and consider their use as medically necessary when the following criteria have been met:

- A diagnosis of opioid abuse and/or dependency exists
- Prescriptions are written by a physician with an appropriate DEA number associated with an "X" prefix

- Patients do not have active prescriptions for other opioids while concurrently taking Suboxone / Subutex
- Patients have not had more than two failures of Suboxone treatment requiring restarting within a year

Suboxone / Subutex will not be covered for the primary treatment of pain.

Note: Documented diagnosis of addiction must be confirmed by the treating physician.

Safety

CareSource will only review requests for Suboxone / Subutex if the patient has none of the following contraindications:

- Hypersensitivity to buprenorphine or naloxone
- Younger than 16 years of age

Caution should be exercised in patients with the following:

- Respiratory disorders
- Dysfunctions of the biliary tract
- Severe renal impairment
- Myxedema
- Adrenal cortical insufficiency
- CNS depression or coma
- Toxic psychoses
- Prostatic hypertrophy or urethral stricture
- Acute alcoholism
- Delirium tremens
- Kyphoscoliosis

Pregnancy Risk Factor = C

There are no adequate and well-controlled studies in pregnant women. Use during pregnancy only if the potential benefit justifies the potential risk to the fetus.

An apparent lack of milk production during general reproduction studies with buprenorphine in rats caused decreased viability and lactation indices. Use of high doses of sublingual buprenorphine in pregnant women showed that buprenorphine passes into the mother's milk. Therefore, breast-feeding is not advised

Neonatal withdrawal: Neonatal withdrawal has been reported in infants of women treated with buprenorphine during pregnancy. From postmarketing reports, the time to onset of neonatal withdrawal symptoms ranged from day 1 to day 8 of life, with most occurring on day 1. Adverse events associated with

neonatal withdrawal syndrome included hypertonia, neonatal tremor, neonatal agitation, and myoclonus. There have been reports of convulsions, apnea, respiratory depression, and bradycardia

Physician Requirements

The following treatment guidelines are expected to be followed by all physicians prescribing Suboxone

- Prescribing physicians will monitor the state’s reporting system for patients being treated (e.g. Ohio – OARRS)
- Patients will be seen by the prescribing physician monthly at a minimum for the first 3 months and no less frequently than every 2 months thereafter
- Suboxone management should be billed using the standard office E & M codes, typically 99212 – 99215, or 90862 pharmacologic management, or 90805 or 90807 individual psychotherapy with E & M
- All patients receiving Suboxone should be actively engaged in therapeutic counseling either by treating physician or by a skilled consultant
- Associated counseling should be billed using standard individual management counseling codes 99401 – 99404, or 90806, 90808, or 90853 depending on time spent
- If individual counseling codes are billed, the E & M code or pharmacologic management code should not be billed and will not be reimbursed
- If counseling is referred outside the office, only E & M or pharmacologic management codes should be billed
- Urine screening should be obtained as indicated using qualitative urine screening only, CPT 80101, or other tests only if specifically indicated
- Suboxone management is a covered service for CareSource members. Since it is a covered service, the treating physician may not bill or balance bill the member for provided services and may not request a signed waiver committing the patient to payment arrangements other than the standard reimbursement provided by CareSource as outlined above

Conditions of Coverage

Quantity Limitations	Maximum Dose of 24 mg/day
Authorization Period	Approved initial authorizations are valid for 60 days. Individual prescriptions will be for no more than a 30 day period. Continued treatment may be considered after review of the medical records and progress notes from the previous 6 month period. ALL authorizations are subject to continued eligibility.

D. REVIEW / REVISION HISTORY

08/1/2011

E. REFERENCES

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The medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.