



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: buprenorphine, buprenorphine/naloxone

Brand Name: Subutex, Suboxone

Medication Class: opioid receptor partial agonist/antagonist

FDA Approved Uses: treatment of opioid dependence

Usual Dose: Doses can vary widely

Subutex: buprenorphine 2 and 8mg/tablet

Suboxone: buprenorphine 2mg / naloxone 0.5mg/tablet

Buprenorphine 8 mg/ naloxone 2mg/tablet

-- Induction† Days 1-7

Patients on short acting opioids should wait a minimum time of 12-24 hours since the last use of opioids before beginning induction. Patients on long acting opioids should wait for 24 hours.

Day 1: Total amount of buprenorphine should not exceed 8mg in the first day.

Patients on short acting opioids- Suboxone 4/1 – 8/2 mg (pregnant women receive Subutex-buprenorphine.

Patients on long acting opioids- Subutex 2mg for the first dose. If patient develops signs or symptoms of withdrawal after the first dose, a second dose of 2mg should be administered and repeated, if necessary, up to a maximum of 8mg.

Note: if withdrawal symptoms are not relieved after a total of 8mg of buprenorphine on day 1, a non-opioid may be administered for symptomatic relief.

Day 2 – Patients that are not pregnant should be switched to Suboxone.

Suboxone-Begin with whatever the established dose was on Day 1 of buprenorphine. Total daily dose of buprenorphine should not exceed 16mg/day. Doses may be increased in 2/0.5 mg to 4/1 mg increments each day, if needed for symptomatic relief, with a target dose of 12/3 to 16/4 mg per day to be achieved within the first week, unless side effects occur. For patients who experience withdrawal symptoms they should receive an equivalent initial dose of Suboxone that was administered on day 1 plus an additional 4/1 mg (maximum initial dose of 12/3mg). If withdrawal symptoms are still present 2 hours after the dose, an additional 4/1 mg dose may be administered.

Day 3-7 - Continue with whatever the established dose was of Suboxone on Day 2. If patient experiences no relief of withdrawal symptoms continue dose increase up to a maximum of 32/8 mg per day.



-- Titration/Stabilization#:

Induction is completed and the stabilization phase is begun when the patient is experiencing no withdrawal symptoms, minimal or no side effects, and no longer has uncontrollable cravings for opioid agonists.

Dosage adjustments may be necessary during early stabilization, and frequent contact with the patient increases the likelihood of compliance.

Suboxone may be increased in 2/0.5mg – 4/1mg increments per week until stabilization is achieved. Nearly all patient will stabilize on daily doses of 16/4-24/6mg, however, some may require up to 32/8mg daily.

-- Dose Reduction/Stopping therapy#:

The decision to discontinue therapy with Subutex or Suboxone should be made as part of a comprehensive treatment plan. Both gradual and abrupt discontinuations have been used. No controlled trials have been undertaken to determine the best method of dose taper at the end of treatment.

Duration of Therapy: For induction and maintenance therapy.

Criteria for Use: (bullet points below are all inclusive unless otherwise noted)

- Must have opioid dependence
- Must be 16 years old or over
- Prescribing physician must have met qualifying requirements and have notified the Secretary of Health and Human Services (HHS) of their intent to prescribe this product for the treatment of opioid dependence. Physician must be listed on the Buprenorphine Physician Locator maintained by the Substance Abuse and Mental Health Services Administration (SAMSHA).
- Use of Subutex for therapy should be limited to patients who cannot tolerate Suboxone.*
- During the induction period, the patient should receive medication under the doctor's supervision in the office. (Induction doses may be obtained through physician's own supply or through a pharmacy.)
- Patient must not be using short or long acting narcotics concurrently with Suboxone/Subutex.

Not approved if:

- Patient has any contraindication to the use of buprenorphine or buprenorphine/naloxone
- Patient does not meet the above criteria.
- Patient is using short or long acting narcotics concurrently with Suboxone/Subutex.

*The consensus panel recommends that the buprenorphine/naloxone combination be used for induction treatment, stabilization and maintenance for most patients.

Patients that should receive Subutex (buprenorphine) include:

- Pregnant women and they should be inducted and maintained with Subutex.
- Patients that cannot tolerate naloxone.
- Patients changing from long acting opioids should use Subutex for induction and then be changed to Suboxone (Buprenorphine/naloxone) as early in treatment as possible.

When buprenorphine monotherapy is used for induction, it is recommended that it be used for no more than 2 days before switching to the buprenorphine/naloxone combination formulation (for patient who are not pregnant)



† *Induction:* The goal of induction is to safely suppress opioid withdrawal as rapidly as possible with the minimum dose of Suboxone or Subutex and experiences no withdrawal symptoms, minimal or no side effects, and no craving for the drug of abuse. This phase is to help a patient begin the process of switching from the opioids of abuse to buprenorphine.

‡ *Stabilization:* This phase begins when the patient is experiencing no withdrawal symptoms, is experiencing minimal or no side effects, and no longer has uncontrollable cravings for opioid agonists. During stabilization, the patients Suboxone is fine-tuned. The goal is to find the minimum dose necessary to keep the patient in treatment. After each dose adjustment, 3-7 days should be allowed for steady state blood levels to be achieved. Stabilization can last anywhere from a week to several weeks.

Dose reduction/stopping therapy: Significant withdrawal symptoms are unusual during gradual Suboxone or Subutex dose taper. The rate of dose reduction should be determined in collaboration with the physician and patient.

P&T Approval: _____ Date: _____