



Prior Authorization Approval Criteria

Suboxone Film (buprenorphine/naloxone)

Generic name:	Buprenorphine/naloxone
Brand name:	Suboxone Film
Medication class:	Opioid receptor partial agonist/antagonist
FDA-approved uses:	Treatment of opioid dependence
Available dosage forms:	8mg/2mg and 2mg/0.5mg film
Usual dose:	Recommended daily dose for maintenance is 16mg/4mg. Maximum daily dose studied was 32mg/8mg.
Approximate monthly cost: (based on AWP 2011)	\$434.40 per month based on recommended dose
Duration of therapy:	Indefinite

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

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Must have opioid dependence
- Must be 16 years of age or older.
- 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).
- Patient must not be using short or long acting narcotics concurrently with Suboxone/Subutex.
- Patient must have a documented severe adverse reaction to the inactive ingredients in Suboxone sublingual tablets that prevents treatment

Criteria for continuation of therapy:

- Patient is not using short or long acting narcotics concurrently

Caution:

- Suboxone film and Suboxone tablets are not bioequivalent. Dose adjustments may be necessary. Buprenorphine exposure from Suboxone film was shown to be higher than the exposure from Suboxone tablets

Contraindication:

- Hypersensitivity to buprenorphine or naloxone

Not approved if:

- Does not meet the above stated criteria.
- Being used for convenience or taste preference

- Being used for the treatment of pain
- Patient is using short or long acting narcotics concurrently with Suboxone/Subutex.

Special considerations:

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.

FCHP Pharmacy and Therapeutics Committee approval: _____

* *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.

Date: _____

Adopted: 03/09/11