MEDICATION POLICY

Generic Name: Buprenorphine/Naloxone Film

Therapeutic Class or Brand Name: Suboxone® Film

Applicable Drugs (if Therapeutic Class)**:** N/A

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 7/18/17

GPI Code: 65200010208220, 65200010208230, 65200010208240, 65200010208250

Prior Authorization Criteria (may be considered medically necessary when criteria I through VI are met):

I. Documented diagnosis of opioid dependence.

II. Prescribing physician must provide his/her X-DEA number.

III. Must supply evidence of plans for on-going treatment monitoring that includes drug urine screening and checking of controlled substance database and/or reports if available.

IV. Must provide description of the counseling and psychosocial support to be received by patient, as indicated by chart notes or a brief letter of medical necessity.

V. Need to provide a treatment plan that includes a tapering plan or discontinuation of pharmacotherapy.

VI. Minimum age requirement: 16 years old.

Exclusion Criteria:

- No concomitant therapy with Vivitrol® (naltrexone) or opiate analgesics is allowed.

Other Criteria:

- Documentation must be provided from progress notes. If the provider desires to provide additional information or detail, a letter of medical necessity will be accepted as a supplement to, but not a replacement for, progress notes.

Quantity/Days Supply Restrictions:

- The maximum dose of Suboxone® Film is 24mg/6mg per day. The quantity is limited to a maximum of a 30 day supply per fill:
  - 2mg/0.5mg: Up to 360 films per 30 days.
  - 4mg/1mg: Up to 180 films per 30 days.
  - 8mg/2mg: Up to 90 films per 30 days.

- 12mg/3mg: Up to 60 films per 30 days.

Approval Length:

- **Authorization:** Initial 18 month authorization at a maximum of 24mg/6mg buprenorphine/naloxone per day.
- **Re-Authorization:**
  - 18 months at a maximum of 24mg/6mg buprenorphine/naloxone per day, if the following criteria a through f are met:
    a. Letter of explanation detailing why an additional approval is needed.
    b. No concomitant therapy with Vivitrol® (naltrexone) or opiate analgesics.
    c. Evidence of counseling and psychosocial support received by patient.
    d. Evidence that a taper plan has been attempted, and if failed, why.
    e. Detailed plans for immediate taper if initial taper failed.
    f. A negative urine screen completed within 14 days of reauthorization start date.

Appendix:

N/A

References:

1. https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Buprenorphine_Naloxone.pdf.
2. NPS.
3. http://www.suboxone.com/content/pdfs/SuboxonePI.pdf.

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Historical Tracking Of Changes Made To Policy	
7/18/2017	1. **Removed** "NOTE: Treatment will only be covered up to 36 months (18 month initial authorization and 18 month re-authorization). After 36 months, NO petitions will be approved under ANY circumstances" **under Re-Authorization under Approval Length**. 2. **Updated** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Suboxone&Zubsolv&Bunavail.pdf" **to** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Buprenorphine_Naloxone.pdf" **under References**.
3/15/2016	1. **Changed policy name from** "Suboxone" **to** "Suboxone Film". 2. **Changed Generic Name from** "Buprenorphine/Naloxone" **to** "Buprenorphine/Naloxone Film". 3. **Changed Therapeutic Class or Brand Name from** "Suboxone®" **to** "Suboxone® Film". 4. **Changed** "…Suboxone®…" **to** "…Suboxone® Film…" **under Quantity/Days Supply Restrictions**.
2/24/2016	1. **Changed GPI Code from** "6520001020" **to** "65200010208220, 65200010208230, 65200010208240, 65200010208250". 2. **Changed** "III. Must supply evidence of plans for on-going treatment monitoring that includes drug urine screening, DOPL reports, or random pill counts" **to** "III. Must supply evidence of plans for on-going treatment monitoring that includes drug urine screening and checking of controlled substance database and/or reports if available" **under Prior Authorization Criteria**. 3. **Changed** "IV. Must provide description of the psychosocial support to be received…" **to** "IV. Must provide description of the counseling and psychosocial support to be received…" **under Prior Authorization Criteria**. 4. **Changed** "The quantity is limited to a maximum of a 30 day supply per fill." **to** "The quantity is limited to a maximum of a 30 day supply per fill: 2mg/0.5mg: Up to 360 films per 30 days; 4mg/1mg: Up to 180 films per 30 days; 8mg/2mg: Up to 90 films per 30 days; 12mg/3mg: Up to 60 films per 30 days" **under Quantity/Days Supply Restrictions**. 5. **Changed** "c. Evidence of psychosocial support received by patient" **to** "c. Evidence of counseling and psychosocial support received by patient" **following Re-Authorization under Approval Length**.
5/20/2015	1. **Removed** "NDC changes for dosage tapering must be submitted in an updated letter of medical necessity" **from Other Criteria**. 2. **Changed** "30 films per 30 days" **to** "The maximum dose of Suboxone® is 24mg/6mg per day. The quantity is limited to a maximum of a 30 day supply per fill" **under Quantity/Days Supply Restrictions**. 3. **Changed** "b. No claims data showing concomitant use of opiates may be present" **to** "b. No concomitant therapy with Vivitrol® (naltrexone) or opiate analgesics" **under Re-Authorization under Approval Length.** 4. **Updated** "http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/Suboxone_&_Zubsolv.pdf" **to** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Suboxone&Zubsolv&Bunavail.pdf" **under References**. 5. **Removed** "blue.regence.com/trgmedpol/drugs/dru224.pdf" **from References** (link no longer valid).
1/20/2014	1. **Adapted policy to new format**. 2. **Changed Quantity/Days Supply Restrictions from** "30 tablets or films per 30 days" **to** "30 films per 30 days". 3. **Changed** "maximum of 24mg/day" **to** "maximum of 24mg/6mg buprenorphine/naloxone per day" **under Authorization under Approval Length**. 4. **Changed** "maximum of 24mg/day" **to** "maximum of 24mg/6mg buprenorphine/naloxone per day" **under Re-Authorization under Approval Length**. 5. **Updated references** to include updated website address for Utah Medicaid policy and package insert.

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Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgment in providing the most appropriate care for their patients.