NC Division of Medical Assistance **Medicaid and Health Choice**
Outpatient Pharmacy **Amended Date:**
Prior Approval Criteria
Opioid Dependence Therapy Agents

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Therapeutic Class Code: H3W

Therapeutic Class Description: Opioid Dependence Therapy Agents

Medication	Generic Code Number(s)	NDC Number(s)
Suboxone® Film	28958, 28959, 33741, 33744	
buprenorphine/naloxone tablets	18973, 18974	
buprenorphine tablets	64672, 64673	
Zubsolv®	34904, 34905, 37823, 37824, 39394, 42843	
Bunavail®	36677, 36678, 36679	

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.
EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- that is unsafe, ineffective, or experimental/investigational.
- that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

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Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's

documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to
correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements
EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. Additional information on EPSDT guidelines may be accessed at http://www.ncdhhs.gov/dma/epsdt/.

Criteria:

Suboxone® Film (completion of prior approval form is not necessary)

Prescription must be written by a physician who has an "X"DEA number[A].

~~**AND**~~

- Beneficiary must have a diagnosis of opioid dependence.

~~**AND**~~

- Physician must have reviewed the Controlled Substances Reporting System Database prior to writing the prescription to ensure that concomitant opioid or ~~benzodiazepine~~ use is not occurring.
- Maximum daily dose of 24 mg/day (Suboxone and buprenorphine/naloxone).
- ~~**Initial** prescriptions for **preferred products** that are 24mg/day or less and are for a 14 day supply or less do not require a prior approval.~~
- ~~A prior approval is required for all subsequent fills.~~
- ~~Prior approval requests for combination products can be approved for up to 12 months.~~
- ~~Renewal requests require a treatment plan.~~

buprenorphine /naloxone tablets, Zubsolv® and Bunavail® (requires trial and failure of Suboxone Film or a medical reason the beneficiary cannot use Suboxone Film)

- Prescription must be written by a physician who has an "X"DEA number[A].

~~AND~~

- Beneficiary must have a diagnosis of opioid dependence.

~~**AND**~~

- Physician must have reviewed the Controlled Substances Reporting System Database prior to writing the prescription to ensure that concomitant opioid or ~~benzodiazepine~~ use is not occurring.

- Maximum daily dose of 24 mg/day (buprenorphine/naloxone).
- Maximum daily dose of 17.1mg/day (Zubsolv).
- Maxium daily dose of 12.6mg/day (Bunavail).
- Requests for combination products can be approved for up to 12 months.
- ~~Renewal requests require a treatment plan.~~

buprenorphine (single ingredient products) (requires prior approval)

- Prescription must be written by a physician who has an "X"DEA number[A].

~~**AND**~~

- Beneficiary must have a diagnosis of opioid dependence.

~~**AND**~~

- Beneficiary must be unable to take Suboxone Film®. Acceptable reasons include:
  - Beneficiaries who are pregnant or breast feeding. (Please provide documentation)
  - Allergy to naloxone which includes the following signs and symptoms: rashes, hives, pruritis, bronchospasm, angioeurotic edema and anaphylactic shock. (Documentation required)

~~**AND**~~

- Requests for buphrenorphine (single ingredient) products may be approved for up to 12 months for beneficiaries with allergies to naloxone.

- Requests for buphrenorphine (single ingredient) products may be approved for up to 9 months during pregnancy and in 2 month increments thereafter during breast feeding.

- Maximum daily dose of 24 mg/day

~~**AND**~~

- Initial requests and renewals require documentation as to why the beneficiary cannot use a combination product.
- ~~Renewal requests require a treatment plan~~.

~~**AND**~~

- Physician must have reviewed the Controlled Substances Reporting System Database prior to writing the prescription ~~to ensure that~~ concomitant opioid ~~or benzodiazepine~~ use is not occurring.~~[B]~~

References

1. Package Insert-Suboxone®, Subutex®, Reckitt Benckiser Pharmaceuticals, Inc., Richmond VA 23235.
2. Narcotic Agonist-Antagonist Analgesics. Drug Facts and Comparisons, Drug Facts and Comparisons, Wolters Kluwer Health. St. Louis (MO): updated monthly.
3. www.suboxone.com

4. Package Insert – Zubzolv® 2013 Orexo US, Inc. All rights reserved. Revised 7/2013

5. Package Insert- Bunavail ® June 2014 BioDelivery Science International, Inc. Raleigh, NC USA 27607

A. "Under the Drug Addiction Treatment Act (DATA 2000) codified at 21 U.S.C. 823 (g), prescription use of buprenorphine sublingual tablets in the treatment of opioid dependence is limited to physicians who meet certain 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".[1] "The Drug Enforcement Administration (DEA) assigns the physician a special identification number that starts with "X". This ID number is required to be included on all buprenorphine prescriptions for opioid addiction therapy, along with the physician's regular DEA registration number."[3]

- SAMHSA at (866)287-2728 (866-BUP-CSAT) can verify if a physician has a valid DATA 2000 waiver
- Contact the physician directly to obtain the DEA registration certificate containing the "X" identifier.

B. "Significant respiratory depression has been associated with buprenorphine, particularly by the intravenous route. A number of deaths have occurred when addicts have intravenously misused buprenorphine, usually with benzodiazepines concomitantly. Deaths have also been reported in association with concomitant administration of buprenorphine with other depressants such as alcohol or other opioids."[1]

"The most common reported side effects for SUBOXONE include headache (36% vs 22% placebo), withdrawal syndrome (25% vs 37% placebo), pain (22% vs 19% placebo), nausea (15% vs 11% placebo), insomnia (14% vs 16% placebo), and sweating (14% vs 10% placebo)." "When SUBOXONE is taken sublingually as prescribed, the naloxone is not absorbed into the bloodstream sufficiently to have any effect. However, if the tablet is crushed and injected by someone who either has recently used or is dependent on a full opioid agonist (eg, morphine, methadone, or heroin), the naloxone will cause that person to experience opioid withdrawal symptoms."[3]

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Criteria Change Log	
08/01/2011	Criteria effective date
06/15/2012	Added Suboxone® Film
08/15/2014	Added Zubsolve®
03/02/2015	Added Bunavail®
	Added exemption from PA criteria for first fill of preferred agent if 14 days or less. Added criteria for single ingredient coverage for naloxone allergy or pregnancy/breastfeeding. Added Zubsolv GCN.
	PA Criteria Name Change from Buprenorphine and Buprenorphine/Naloxone to Opioid Dependence Therapy Agents
	Remove PA requirement on Suboxone Film