

**NC Division of Medical Assistance  
 Outpatient Pharmacy  
 Prior Approval Criteria  
 Buprenorphine and Buprenorphine/Naloxone**

**Medicaid and Health Choice  
 Amended Date: March 2, 2015**

**Therapeutic Class Code:** H3W

**Therapeutic Class Description:** Narcotic Agonist-Antagonist Analgesics

Medication	Generic Code Number(s)	NDC Number(s)
Suboxone, buprenorphine/naloxone	18973, 18974	
Subutex, buprenorphine	64672, 64673	
Suboxone Film	28958, 28959, 33741, 33744	
Zubsolv	34904, 34905, 37821, 37823, 37824, 39394	
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

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

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,

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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/buprenorphine /naloxone, Zubsolv and Bunavail

- Prescription must be written by a physician who has an “X”DEA number. <sup>A</sup>

**AND**

- Beneficiary must have a diagnosis of opioid dependence.

**AND**

- Physician must have reviewed the Controlled Substances Reporting System Database prior to writing Suboxone prescription to ensure that concomitant narcotic or benzodiazepine use is not occurring. <sup>B</sup>
- Maximum daily dose of 24 mg/day (Suboxone and buprenorphine/naloxone).
- Maximum daily dose of 17.1mg/day (Zubsolv).
- Maximum daily dose of 12.6mg/day (Bunavail).
- Length of therapy may be approved for up to 12 months. Request for renewal will require a treatment plan.

Subutex and buprenorphine

- Prescription must be written by a physician who has an “X”DEA number. <sup>A</sup>

**AND**

- Beneficiary must have a diagnosis of opioid dependence.

**AND**

- Beneficiary must be unable to take Suboxone. Acceptable reasons include:
  - Beneficiaries who are pregnant.
  - Allergy to naloxone which includes the following signs and symptoms: rashes, hives, pruritis, bronchospasm, angioedema and anaphylactic shock. <sup>C</sup>

**AND**

- Physician must have reviewed the Controlled Substances Reporting System Database prior to writing Subutex or buprenorphine prescription to ensure that concomitant narcotic or benzodiazepine use is not occurring. <sup>B</sup>
- Maximum daily dose of 24mg/day.
- Length of therapy may be approved for up to 12 months. Request for renewal will require a treatment plan.

References

1. Package Insert-Suboxone<sup>®</sup>, Subutex<sup>™</sup>, 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](http://www.suboxone.com)
4. Package Insert – Zubzolv<sup>®</sup> 2013 Orexo US, Inc. All rights reserved. Revised 7/2013
5. Package Insert- Bunavail<sup>®</sup> 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”.<sup>1</sup> “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.”<sup>3</sup>

- 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.”<sup>1</sup>

C. “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.”<sup>3</sup>