NC Medicaid Outpatient Pharmacy Prior Approval Criteria Opioid Dependence Therapy Agents	Medicaid and Health Choice Effective Date: August 1, 2011 Amended Date~~: October 1, 2022~~

Therapeutic Class Code: H3W

Therapeutic Class Description: Opioid Dependence Therapy Agents

Medication
Suboxone® Film
Sublocade™
buprenorphine/naloxone tablets
buprenorphine/naloxone film
buprenorphine tablets
Zubsolv®

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.

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

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide,* sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***NCTracks Provider Claims and Billing Assistance Guide*:**
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page:
https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Claims should not automatically be denied at point of sale due to lack of a diagnosis of (or history of) opioid use disorder on the beneficiary's file

Criteria:

Suboxone® Film and buprenorphine /naloxone tablets (completion of prior approval form is not necessary)

- ~~Prescription must be written by a prescriber who has an "X"DEA number[A].~~
- Beneficiary must have a diagnosis of opioid dependence.
- Prescriber must have reviewed the Controlled Substances Reporting System Database prior to writing the prescription to ensure that concomitant opioid use is not occurring.
- Maximum daily dose of 24mg/day (Suboxone Film and buprenorphine/naloxone tablets). For daily doses between 24mg and up to 32mg, a pharmacist may override the edit at point-of-sale after consulting the

prescriber to determine the clinical need for the higher dose. Documentation is to be made in the NCPDP pharmacy system or on the original prescription.

Sublocade® (completion of prior approval form is not necessary)

- ~~Prescription must be written by a prescriber who has an "X"DEA number~~[A].
- Beneficiary must have a diagnosis of opioid dependence.
- Prescriber must have reviewed the Controlled Substances Reporting System Database prior to writing the prescription to ensure that concomitant opioid use is not occurring.
- Beneficiary must have received treatment with a transmucosal buprenorphine-containing product for a minimum of 7 days before using Sublocade.
- Maximum dose of two monthly initial doses of 300 mg followed by 100 mg monthly maintenance doses.

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

- ~~Prescription must be written by a prescriber who has an "X"DEA number~~[A].
- Beneficiary must have a diagnosis of opioid dependence.
- Prescriber must have reviewed the Controlled Substances Reporting System Database prior to writing the prescription to ensure that concomitant opioid or use is not occurring.

- Maximum daily dose of 24mg/day (buprenorphine/naloxone). For daily doses between 24mg and up to 32mg, a pharmacist may override the edit at point-of-sale after consulting the prescriber to determine the clinical need for the higher dose. Documentation is to be made in the NCPDP pharmacy system or on the original prescription.

- Maximum daily dose of 11.4 mg/day (Zubsolv). For daily doses between 11.4mg and up to 17.2mg, a pharmacist may override the edit at point-of-sale after consulting the prescriber to determine the clinical need for the higher dose. Documentation is to be made in the NCPDP pharmacy system or on the original prescription.

- Requests for combination products can be approved for up to 12 months.

buprenorphine (single ingredient products) (requires prior approval)

- ~~Prescription must be written by a prescriber who has an "X"DEA number~~[A].
- Beneficiary must have a diagnosis of opioid dependence.
- Beneficiary must be unable to take a buprenorphine/naloxone combination product. 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)
- 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. For daily doses between 24mg and up to 32mg a pharmacist may override the edit at point-of-sale after consulting the prescriber to determine the clinical need for the higher dose. Documentation is to be made in the NCPDP pharmacy system or on the original prescription.
- Initial requests and renewals require documentation as to why the beneficiary cannot use a combination product.
- Prescriber must have reviewed the Controlled Substances Reporting System Database prior to writing the prescription to ensure that concomitant opioid 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
6. Package Insert- Sublocade™ Revised January 2018 Indivior, Inc. North Chesterfield, VA

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®
11/01/2017	Added criteria for single ingredient coverage for naloxone allergy or pregnancy/breastfeeding. Added Zubsolv® GCN. PA Criteria Name Changed from Buprenorphine and Buprenorphine/Naloxone to Opioid Dependence Therapy Agents Removed PA requirement on Suboxone Film®
06/05/2018	Changed Physician to Prescriber Add Sublocade™
10/01/2018	Maximum Dose Limits with Overrides
11/21/2019	Added generic buprenorphine /naloxone film
10/01/2022	Remove Bunavail (off market) Increase maximum dose Suboxone to 32mg
10/01/2022	Moved buprenorphine /naloxone tablets as preferred to align with the PDL
xx/xx/xxxx	Claims should not automatically be denied at point of sale due to lack of a diagnosis of (or history of) opioid use disorder on the beneficiary's file Removed X-DEA requirement because no longer a ruling