NC Medicaid Outpatient Pharmacy Prior Approval Criteria Opioid Analgesics	Medicaid and Health Choice Effective Date: March 4, 2002 Amended Date: ~~July 9, 2020~~

Therapeutic Class Code: H3A,H3N
Therapeutic Class Description: Analgesics, Opioids; Analgesics, Opioid Agonist, NSAID Combination

Medication (Short Acting)
Abstral
Actiq and generic fentanyl citrate lozenges
Apadaz tablet and generic benzhydrocodone-acetaminophen tablet
Ascomp
butalbital-caffeine-acetaminophen with codeine
butorphanol spray
Capital with codeine suspension
Codeine sulfate
Demerol and generic meperidine
dihydrocodeine-acetaminophen-caffeine
Dilaudid and generic hydromorphone
Dsuvia
Fentora
Fiorinal with codeine and generic butalbital compound with codeine
hydrocodone/acetaminophen
hydrocodone/ibuprofen
Ibudone and generic hydrocodone/ibuprofen
Lazanda
Lorcet and generic hydrocodone/acetaminophen
Lortab and generic hydrocodone/acetaminophen
Levorphanol
morphine
Nalocet
Norco and generic hydrocodone/acetaminophen
Nucynta

Opana and generic oxymorphone
Oxaydo
oxycodone
oxycodone/acetaminophen
oxycodone/aspirin
oxycodone/ibuprofen
pentazocine-naloxone
Percocet and generic oxycodone/acetaminophen
PrimLev
Roxybond
Roxicodone and generic oxycodone
Subsys
Tylenol with codeine and generic acetaminophen with codeine
Ultracet and generic acetaminophen with tramadol
Ultram and generic tramadol
Vicodin and generic hydrocodone/acetaminophen
Xylon and generic hydrocodone/ibuprofen

Medication (Long Acting)
Arymo ER
Belbuca
Butrans and generic buprenorphine patch
Conzip and generic tramadol ER capsule
Dolophine and generic methadone
Duragesic and generic fentanyl
Embeda
Exalgo and generic hydromorphone ER
Hysingla ER
Kadian and generic morphine sulfate ER
MS Contin and generic morphine sulfate ER

MorphaBond ER
morphine sulfate ER
Nucynta ER
Oxycontin and generic oxycodone ER
oxymorphone ER
tramadol ER
Xtampza ER
Zohydro ER Capsules and generic hydrocodone ER

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, 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.

***Basic Medicaid and NC Health Choice Billing Guide*:** ~~https://medicaid.ncdhhs.gov/~~ https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page: ~~https://medicaid.ncdhhs.gov/~~ 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 NC Medicaid clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Exemptions:
Prior authorization is not required for beneficiaries with a diagnosis of pain secondary to cancer.

Prior authorization is not required on preferred short-acting opioids up to the equivalent daily maximum dose of 90 MME/day for beneficiaries with Sickle Cell Disease.

Criteria:

Short-Acting preferred Opioid Analgesics

- Prior approval is required for total daily doses greater than the equivalent daily maximum dose of 90 MME/day ~~than the maximums listed in~~ (Table 1) or greater than the maximum daily dose per claim (Table 3).

- Prior approval is required for greater than 5 days supply for acute pain and 7 days supply for postoperative pain.

- Prior approval requests should include the beneficiary's diagnosis and reason for exceeding dose per day limits and duration (days supply) limits.

- Prior approval requests may be approved for up to 6 months

- Reauthorization prior approval requests for beneficiaries with chronic pain must include documentation as to why the beneficiary needs continued opioid treatment and current plan of care

- The prescribing clinician shall review the North Carolina Medical Board statement on use of controlled substances for the treatment of pain (https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/Policy_for_the_use_of_opiates_for_the_treatment_of_pain) and is adhering as medically appropriate to the guidelines which include: (a) complete beneficiary evaluation, (b) establishment of a treatment plan (contract), (c) informed consent, (d) periodic review, and (e) consultation with specialists in various treatment modalities as appropriate.

- The prescribing clinician shall check the beneficiary's utilization of controlled substances on the NC Controlled Substance Reporting System. (https://northcarolina.pmpaware.net/login).

- The prescribing clinician shall review the CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. (https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm).

Short-Acting Non-preferred Opioid Analgesics

- Prior approval required for all non-preferred short acting-opioids

- Prior approval is required for total daily doses greater than the equivalent daily maximum dose of 90 MME/day ~~than the maximums listed in~~ (Table 1) or greater than the maximum daily dose per claim (Table 3).

- Prior approval required for greater than 5 days supply for acute pain and 7 days supply for postoperative pain.

- Prior approval requests should include the beneficiary's diagnosis and reason for exceeding dose per day limits and duration (days supply) limits.

- Reauthorization prior approval requests for beneficiaries with chronic pain must include documentation as to why the beneficiary needs continued opioid treatment and current plan of care

- Prior approval requests may be approved for up to 6 months.

- The Beneficiary must have a documented failure within the past year of ~~t~~two preferred opioid analgesics at a dose equivalent to the dose of the product being prescribed or a known documented contraindication to one or more of the preferred ingredients (i.e. dye). The nature of treatment failure must be clearly documented in the chart

- The prescribing clinician shall review the North Carolina Medical Board statement on use of controlled substances for the treatment of pain (https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/Policy_for_the_use_of_opiates_for_the_treatment_of_pain), and is adhering as medically appropriate to the guidelines which include: (a) complete beneficiary evaluation, (b) establishment of a treatment plan (contract), (c) informed consent, (d) periodic review, and (e) consultation with

specialists in various treatment modalities as appropriate.

- The prescribing clinician shall check the beneficiary's utilization of controlled substances on the NC Controlled Substance Reporting System. (https://northcarolina.pmpaware.net/login).

- The prescribing clinician shall review the CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. (https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm).

Long-Acting Preferred Opioid analgesics

- ~~The Beneficiary shall have a diagnosis of chronic pain syndrome of at least four weeks duration.~~

- The beneficiary shall have a diagnosis of moderate to severe pain with need for around-the-clock analgesia for an extended period.

- Prior approval is required for total daily doses greater than the ~~maximums~~ equivalent daily maximum dose of 90 MME/day ~~listed in~~ (Table 2) or greater than the maximum daily dose per claim (Table 3).

- Prior approval is required for beneficiaries who have not tried a short acting opioid in the past 45 days before trying long acting regardless of dose or days supply. Prior approval requests should include reason that beneficiary has not or cannot use a short acting first.

- Prior approval is required for greater than 7 days supply.

- Prior approval requests should include the beneficiary's diagnosis and reason for exceeding limits

- Prior approval requests may be approved for up to ~~12~~ 3 months.

- The prescribing clinician shall review the North Carolina Medical Board statement on use of controlled substances for the treatment of pain (https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/Policy_for_the_use_of_opiates_for_the_treatment_of_pain)
and is adhering as medically appropriate to the guidelines which include: (a) complete beneficiary evaluation, (b) establishment of a treatment plan (contract), (c) informed consent, (d) periodic review, and (e) consultation with specialists in various treatment modalities as appropriate.

- The prescribing clinician shall check the beneficiary's utilization of controlled substances on the NC Controlled Substance Reporting System. (https://northcarolina.pmpaware.net/login).

- The prescribing clinician shall review the CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. (https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm).

Long Acting Non-Preferred Opioid Analgesics

- ~~The Beneficiary shall have a diagnosis of chronic pain syndrome of at least four weeks duration.~~

- The beneficiary shall have a diagnosis of moderate to severe pain with need for around-the-clock

- analgesia for an extended period.
- Prior approval is required for all non-preferred long acting opioids
- Prior approval is required for total daily doses greater than the ~~maximums~~ equivalent daily maximum dose of 90 MME/day ~~listed in~~ (Table 2) or greater than the maximum daily dose per claim (Table 3).
- Prior approval is required for greater than 7 days supply.
- Prior approval requests should include the beneficiary's diagnosis and reason for exceeding limits
- Prior approval requests may be approved for up to ~~12~~ 3 months.
- The Beneficiary must have a documented failure within the past year of two-preferred opioid analgesics at a dose equivalent to the dose of the product being prescribed or a known documented contraindication to one or more of the preferred ingredients (i.e. dye). The nature of treatment failure must be clearly documented in the chart
- The prescribing clinician shall review the North Carolina Medical Board statement on use of controlled substances for the treatment of pain (https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/Policy_for_the_use_of_opiates_for_the_treatment_of_pain) and is adhering as medically appropriate to the guidelines which include: (a) complete beneficiary evaluation, (b) establishment of a treatment plan (contract), (c) informed consent, (d) periodic review, and (e) consultation with specialists in various treatment modalities as appropriate.
- The prescribing clinician shall check the beneficiary's utilization of controlled substances on the NC Controlled Substance Reporting System. (https://northcarolina.pmpaware.net/login).
- The prescribing clinician shall review the CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. (https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm).

Procedures

- Changes in strength will not require prior authorization.
- Prior authorization request forms will be accepted when submitted by facsimile telecommunication or web entry methods only.

Table 1

Short-acting- Daily dose limits for coverage	
Drug	**Dose ~~Limit~~ equivalent to 90 MME/day**
benzhydrocodone	109.8mg/day
butorphanol	12.8mg/day

Short-acting- Daily dose limits for coverage	
Drug	**Dose ~~Limit~~ equivalent to 90 MME/day**
codeine products	~~360 mg/day~~ 600 mg/day
dihydrocodeine	900mg/day
fentanyl citrate buccal, lozenges, sublingual (Abstral, Actiq, Fentora)	692 mcg/day
fentanyl citrate nasal spray (Lazanda)	562 mcg/day
fentanyl sublingual spray (Subsys)	500 mcg/day
hydrocodone/ acetaminophen	~~60mg/day~~ 90 mg/day hydrocodone
hydrocodone	~~60mg/day~~ 90 mg/day
hydromorphone (Dilaudid®)	24mg/day
morphine immediate-release	90mg/day
oxycodone immediate-release	60mg/day
oxycodone/ acetaminophen	60mg/day
oxycodone/aspirin	60mg/day oxycodone
oxycodone/ ibuprofen	60mg/day oxycodone

Short-acting- Daily dose limits for coverage	
Drug	**Dose ~~Limit~~ equivalent to 90 MME/day**
oxymorphone immediate- release (Opana®)	30mg/day
pentazocine	~~27.2mg/day~~ 272 mg/day
tramadol (Ultram® and Ultracet®)	~~900mg/day~~ 400mg/day

NOTE: Dose in chart is equivalent to 90 mg morphine per day. MME values may exceed dosage recommendations. These values do not imply suggested dosing

Table 2

Long-acting daily dose limits for coverage	
Drug	**Dose ~~Limit~~ equivalent to 90 MME/day**
Dolophine®, Methadose® (methadone)	22.5mg/day
Duragesic® (fentanyl transdermal)	37.5µg/hr (one patch every 72 hours)
Embeda® (morphine/naltrexone)	90/3.6 mg/day
Exalgo® (hydromorphone)	24 mg/day
~~Fentanyl (Subsys, Abstral, lozenges, Fentora, Fentora)~~	~~2400 mcg/day~~

Long-acting daily dose limits for coverage	
Drug	**Dose ~~Limit~~ equivalent to 90 MME/day**
Hysingla ER® (hydrocodone extended-release tablet)	~~60 mg/day~~ 90 mg/day
Kadian® (morphine extended-release)	90 mg/day
~~Levo-Dromoran®~~ levorphanol	~~3 mg/day~~ 8.1 mg/day
morphine extended-release capsule	90 mg/day
MS Contin®, Oramorph SR® (morphine controlled-release)	90mg/day
~~Opana® ER oxymorphone extended-release~~	~~30 mg/day~~
OxyContin® (oxycodone controlled-release)	60 mg/day
oxymorphone extended-release	30mg/day
tramadol ER (Conzip® and Ultram ER®)	~~900mg/day~~ 300mg/day
Zohydro ER® (hydrocodone extended-release capsule)	~~60 mg/day~~ 90 mg/day

NOTE: Dose in chart is equivalent to 90 mg morphine per day. MME values may exceed dosage recommendations. These values do not imply suggested dosing

Table 3

Maximum daily dose per claim	
Drug	**Max Dose/Day**
acetaminophen products	4 grams/day Acetaminophen
ibuprofen products	3.2 grams/day ibuprofen
Aspirin products	4 grams/day aspirin
tramadol (Ultram® and Ultracet®)	400mg/day
tramadol ER (Conzip® and Ultram ER®)	300mg/day

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Criteria Change Log

03/04/2002	Criteria effective date- (original name Oxycontin)
08/04/2008	Name changed to Schedule II Narcotics
10/11/2012	Add Nucynta ER
03/13/2014	Add Zohydro
12/08/2014	Add Butrans NDC's
03/03/2015	Add new oxycodone GCN's
05/18/2015	Add Hysingla
06/10/2015	Add Embeda/Exalgo
06/16/2015	Add new morphine NDC's
01/21/2016	Add Lazanda, Oxecta
06/16/2016	Add Belbuca
08/27/2017	Dose limits changed to 120mme/day and limits added for 14 days supply
01/02/2018	limits added for 5 and 7 days supply
06/01/2018	Change daily limit to 90 mme and add CIII and CIV's
11/20/2018	Remove special criteria for Zohydro
02/13/2019	Add Roxybond
07/12/2019	Add Nalocet
09/17/2019	Add tramadol ER dose limits to chart. Were already programmed but only put in short acting chart originally. Add Apadaz and add benzhydrocodone MME's to chart Moved Conzip to Long Acting
07/09/2020	Updated EPSDT links Removed GCN's Added exemption for Sickle Cell for short acting opioids at 90mme's or less/day
xx/xx/xxxx	Removed obsolete products: Avinza, Endodan, Fioricet with codeine, Hycet, Magnacet, Onsolis, Oxecta, Percodan, Synalgos-DC & generic, Ultram ER, Vicoprofen, Xartemis XR, Xodol, Reprexain, and Zamicet Added: benzhydrocodone/APAP (generic Apadaz), Dsuvia, hydrocodone/ibuprofen (generic Ibudone), morphine sulfate ER (generic Avinza), buprenorphine patch (generic Butrans), tramadol ER capsule (generic Conzip), Morphabond ER Dose table clarification