NC Division of Medical Assistance **Medicaid and Health Choice**
Outpatient Pharmacy **Effective Date: March 4, 2002**
Prior Approval Criteria **Amended Date: July 9, 2020**
Opioid Analgesics

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
Ascomp
butorphanol spray
Capital with codeine suspension
codeine
oxycodone and ibuprofen
Demerol and generic meperidine
Dihydrocodeine-acetaminophen-caffeine
Dilaudid and generic hydromorphone
Endodan and generic oxycodone and aspirin
Fentora
Fioricet with codeine and generic
Fiorinal with codeine and generic
Hycet and generic hydrocodone/acetaminophen solution
Ibudone
Lazanda
Lorcet and generic hydrocodone/acetaminophen
Lortab and generic hydrocodone/acetaminophen
Levorphanol
Magnacet
morphine

Nalocet
Norco and generic hydrocodone/acetaminophen
Nucynta
Onsolis
Opana and generic oxymorphone
Oxecta (Oxaydo)
oxycodone capsules
oxycodone and acetaminophen caps
pentazocine-naloxone
Percocet and generic oxycodone/acetaminophen
Percodan and generic oxycodone/aspirin
PrimLev
Roxybond
Roxicodone and generic oxycodone
Subsys
Synalgos-DC and generic
Tylenol with codeine and generic acetaminophen with codeine
Ultracet and generic acetaminophen with tramadol
Ultram and generic tramadol
Vicodin and generic hydrocodone/acetaminophen
Vicoprofen and generic hydrocodone/ibuprofen
Xodol and generic hydrocodone/acetaminophen
Xylon and Repraxin and generic hydrocodone/ibuprofen
Zamicet

Medication (Long Acting)
Avinza
Belbuca
Butrans
Conzip
Dolophine and generic methadone
Duragesic and generic fentanyl
Embeda
Exalgo and generic hydromorphone ER
Hysingla ER
Kadian and generic morphine sulfate ER
Nucynta ER
MS Contin and generic morphine sulfate ER
Opana ER and generic oxymorphone ER
Oxycontin and generic oxycodone ER
Ultram ER and generic tramadol ER
Xartemis XR
Xtampza ER
Zohydro ER Capsules

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://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 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 <u>preferred short-acting opioids</u> up to the equivalent daily maximum dose of 90 MME/day for beneficiaries with Sickle Cell Disease.

Prescribers are expected to comply with the STOP Act of 2017.

Criteria:

<u>Short-Acting preferred Opioid Analgesics</u>

- Prior approval is required for total daily doses greater than the maximums listed in Table 1.
- 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).

<u>Short-Acting Non-preferred Opioid Analgesics</u>

- Prior approval required for all non-preferred short acting-opioids
- Prior approval required for total daily doses greater than the maximums listed in Table 1.

- 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.

- Prior approval is required for total daily doses greater than the maximums listed in Table 2.

- 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 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.

- Prior approval is required for all non-preferred long acting opioids

- Prior approval is required for total daily doses greater than the maximums listed in Table 2.

- 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 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**
acetaminophen products	4 grams/day acetaminophen
benzhydrocodone	109.8mg/day
butorphanol	12.8mg/day
codeine products	360 mg/day
dihydrocodeine	900mg/day
hydrocodone/ acetaminophen	60mg/day
hydrocodone	60mg/day hydrocodone
ibuprofen products	3.2 grams/day ibuprofen
hydromorphone (Dilaudid®)	24mg/day
morphine immediate-release	90mg/day
oxycodone immediate-release	60mg/day
oxycodone/ acetaminophen	60mg/day
oxycodone/aspirin	4 grams/day aspirin 60mg/day oxycodone

Short-acting- Daily dose limits for coverage	
Drug	**Dose Limit**
oxycodone/ ibuprofen	3.2 grams/day ibuprofen 60mg/day oxycodone
oxymorphone immediate- release (Opana®)	30mg/day
pentazocine	27.2mg/day
tramadol (Ultram® and Ultracet®)	900mg/day

Table 2

Long-acting daily dose limits for coverage	
Drug	**Dose Limit**
Dolophine®, Methadose® (methadone)	22.5mg/day
Duragesic® (fentanyl transdermal)	37.5µg/hr (i.e. one 50 µg patch every 72
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
Hysingla ER® (hydrocodone extended-release tablet)	60 mg/day
Kadian® (morphine extended-release)	90 mg/day
Levo-Dromoran® (levorphanol)	3 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
Zohydro ER® (hydrocodone extended-release capsule)	60 mg/day

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

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
05/13/2020	Updated EPSDT links Removed GCN's Added exemption for Sickle Cell for short acting opioids at 90mme's or less/day
07/09/2020	Added Prescribers are expected to comply with the STOP Act of 2017.