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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 12, 2019**

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

| Medication (Short Acting) | Generic Code Number(s) | NDC Number(s) |
|---|---|---|
| Abstral | 16178, 16179, 16181-16184 | |
| Actiq and generic fentanyl citrate lozenges | 19191-19194, 19204, 19206 | |
| Ascomp | 69500 | |
| butorphanol spray | 20351 | |
| Capital with codeine suspension | 70110 | |
| codeine | 16240-16242 | |
| Conzip | 30383, 30382, 30384 | |
| oxycodone and ibuprofen | 23827 | |
| Demerol and generic meperidine | 15990-15991 | |
| Dihydrocodeine-acetaminophen-caffeine | 41517 | |
| Dilaudid and generic hydromorphone | 16143, 16141, 16144, 20251 | |
| Endodan and generic oxycodone and aspirin | 26836 | |
| Fentora | 97280-97281, 97283-97285 | |
| Fioricet with codeine and generic | 70140 | |
| Fiorinal with codeine and generic | 69500 | |
| Hycet and generic hydrocodone/acetaminophen solution | 21146 | |
| Ibudone | 22678, 99371 | |




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|---|---|---|
| Lazanda | 27648, 29146, 41539 | |
| Lorcet and generic | 12486, 14288, 70320, 70332, 70333, 70925 | |
| Lortab and generic hydrocodone/acetaminophen | 12486, 20906, 29246, 70330, 70331, 70334, 70338, 70339 | |
| Levorphanol | 16350 | |
| Magnacet | 97873- 97876 | |
| Morphine | 16070-16071, 16051-16053, 16060, 16062, 16063 | |
| Nalocet | 26953 | |
| Norco and generic hydrocodone/acetaminophen | 12486, 12488, 70330 | |
| Nucynta | 26163-26165 | |
| Onsolis | 27545-27549 | |
| Opana and generic oxymorphone | 27243-27244 | |
| Oxecta (Oxaydo) | 31256, 32047 | |
| oxycodone capsules | 16285 | |
| oxycodone and acetaminophen caps | 70500 | |
| pentazocine-naloxone | 71060 | |
| Percocet and generic oxycodone/acetaminophen | 14965-14966, 50756, 50766,70491-70492 | |
| Percodan andgeneric oxycodone/aspirin | 26836 | |
| PrimLev | 26953-26956 | |
| Roxybond | 32047, 44877, 44878 | |
| Roxicodone and generic oxycodone | 16280-16281, 16290, 20091-20092 | |
| Subsys | 31187, 31188, 31189, 31192, 31193, 31196, 31197 | |
| Synalgos-DC and generic | 98183 | |
| Tylenol with codeine and generic | 70134, 70136 | |
| Ultracet and generic | 13909 | |
| Ultram and generic | 07221 | |

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|---|---|---|
| Vicodin and generic hydrocodone/acetaminophen | 22929, 26470, 26709 | |
| Vicoprofen and generic hydrocodone/ibuprofen | 63101 | |
| Xodol and generic hydrocodone/acetaminophen | 22929, 26470, 26709 | |
| Xylon and Repraxin and generic hydrocodone/ibuprofen | 99371 | |
| Zamicet | 99967 | |
| Avinza | 17189, 17191-17193, 16212-16213 | |
| Belbuca | 39959, 39965, 39966, 39967, 39968, 39969, 39975 | |
| Butrans | 25308-25309, 25312, 35214, 36946 | |
| Dolophine and generic | 16420, 16422 | |
| Duragesic and generic | 19200-19203, 24635 | |
| Embeda | 37685, 37686, 37687, 37688, 37689, 37692 | |
| Exalgo and generic hydromorphone ER | 28427, 33088, 33142, 33143 | |
| Hysingla ER | 37539, 37541, 37543, 37544, 37545, 37546, 37547 | |
| Kadian and generic morphine sulfate ER | 26490, 26492-26494, 97534-97535, 97508, 98135, 33158, 33159, 33162, 33164 | |
| Nucynta ER | 29787, 29788, 29789, 29791, 29792 | |
| MS Contin and generic morphine sulfate ER | 16078, 16640-16643 | |
| Opana ER and generic oxymorphone ER | 27247-27249, 27253, 33832, 33833, 33915, 33916, 33917, 33918, 33919, 99492-99494 | |
| Oxycontin and generic | 16282-16284, 16286, 99238-99240 | |
| Ultram ER and generic | 50417, 50427, 26387 | |
| Xartemis XR | 36243 | |
| Xtampza ER | 41272-41276 | |

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|---|---|---|
| Zohydro ER Capsules | 35365, 35504, 35505, 35506, 35507, 35525,<br>38057, 38058, 38059, 38061, 38062, 38063 | |

**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/
**EPSDT provider page:** https://medicaid.ncdhhs.gov/

**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.

**Criteria:**

## Short-Acting preferred Opioid Analgesics

- 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 (http://www.ncmedboard.org/Clients/NCBOM/Public/NewsandForum/mgmt.htm), 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://nccsrsph.hidinc.com).

- 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 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 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://nccsrsph.hidinc.com).

- 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://nccsrsph.hidinc.com).
- 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://nccsrsph.hidinc.com).
- 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 |

| | |
|---|---|
| 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<br>60mg/day oxycodone |

**Short-acting- Daily dose limits for coverage**

| Drug | Dose Limit |
|---|---|
| oxycodone/ ibuprofen | 3.2 grams/day ibuprofen<br>60mg/day oxycodone |
| oxymorphone immediate-release (Opana®) | 30mg/day |
| pentazocine | 27.2mg/day |

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|---|---|
| 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 hours) |
| Embeda® (morphine/naltrexone) | 90/3.6 mg/day |
| Exalgo® | 24 mg/day |

| Long-acting daily dose limits for coverage | |
|---|---|
| **Drug** | **Dose Limit** |
| Fentanyl (Subsys, Abstral, lozenges, Fentora, Fentora | 2400 mcg/day |
| 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 |
| Zohydro ER® (hydrocodone extended- release capsule) | 60 mg/day |

**References**

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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 12, 2019 |
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**Criteria Change Log**

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|---|---|
| 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 additional criteria for Zohydro |
| 02/13/2019 | Add Roxybond |
| 07/12/2019 | Add Nalocet |