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

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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	
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	

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Magnacet	97873- 97876	
morphine	16070-16071, 16051-16053, 16060, 16062, 16063	
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 and generic oxycodone/aspirin	26836	
PrimLev	26953-26956	
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	
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	

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Medication (Long Acting)	Generic Code Number(s)	
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	
Zohydro ER Capsules	35365, 35504, 35505, 35506, 35507, 35525, 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**.

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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, providerdocumentation 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/.

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.

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- 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 ~~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 (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).

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 (http://www.ncmedboard.org/position_statements/detail/policy_for_the_use_of_controlled_substances_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).

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- 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 (http://www.ncmedboard.org/position_statements/detail/policy_for_the_use_of_controlled_substances_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).

~~**Zohydro**~~

- ~~Documented failure of ALL preferred and non-preferred agents (unique product only) required before Zohydro may be utilized.~~

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.

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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 60mg/day oxycodone

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

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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

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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:

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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
	Remove specific criteria Zohydro