Clinical Policy: Age Limit Override (Codeine, Tramadol, Hydrocodone)

Reference Number: CP.PMN.138
Effective Date: 03.13.18
Last Review Date: 05.24
Line of Business: Commercial, HIM, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Prior authorization is required for the following medications in the respective age groups due to FDA labeling of these medications:

- Codeine-containing medications indicated for pain are contraindicated in pediatric patients younger than age 12 years and in patients less than 18 years to treat post-tonsillectomy and post-adenoidectomy pain;
- Tramadol-containing medications are not indicated for pain in patients younger than age 18 years (use is contraindicated in pediatric patients younger than age 12 years and in patients less than 18 years to treat post-tonsillectomy and post-adenoidectomy pain);
- Codeine- and hydrocodone-containing medications indicated for cough and cold are not indicated for use in pediatric patients younger than age 18 years.

FDA Approved Indication(s)
Codeine- and tramadol-containing medications are indicated for the management of mild to moderate pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Limitation(s) of use: Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, reserve codeine- and tramadol-containing medications for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or opioid combination products):

- Have not been tolerated or are not expected to be tolerated;
- Have not provided adequate analgesia or are not expected to provide adequate analgesia.

Codeine- and hydrocodone-containing medications are indicated for relief of cough, nasal congestion, and other upper respiratory symptoms associated with allergies or cold.

Limitation(s) of use: Not indicated for pediatric patients under 18 years of age.

- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve codeine-containing medications for use in adult patients for whom the benefits of cough suppression are expected to outweigh the risks, and in whom an adequate assessment of the etiology of the cough has been made.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that codeine-, tramadol-, and hydrocodone-containing opioids are **medically necessary** for the following reasons:

I. Initial Approval Criteria
Please note: for HIM-Arkansas – if a member's covered prescription pain medication requires a prior authorization, then the prior authorization shall not be denied if the member has a terminal illness.

A. Pain (must meet all):
**In addition to meeting these criteria, requests for all opioids are subject to the criteria outlined in the opioid analgesic policy for the relevant line of business.*
1. Prescribed for pain management;
2. Prescribed agent is FDA-approved for pain management;
3. Member meets one of the following (a or b):
   a. Failure of at least two non-opioid ancillary treatments (e.g., non-steroidal anti-inflammatory drugs [NSAIDs], acetaminophen, anticonvulsants, antidepressants) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
   b. For cancer, palliative care, or sickle cell disease: prescribed by or in consultation with an oncologist, hematologist, hospice provider, or pain specialist;
4. Failure of at least two age-appropriate opioid analgesics (e.g., morphine, oxycodone), unless clinically significant adverse effects are experienced or all are contraindicated;
5. Use is not for pain post-tonsillectomy or post-adenoidectomy;
6. Dose does not exceed health plan's approved quantity limit.

Approval duration:
Non-cancer pain – 7 days
Cancer, sickle cell, or palliative care – 12 months

B. Cough (must meet all):
1. Diagnosis of cough due to viral or bacterial infection;
2. Prescribed agent is FDA-approved for the treatment of cough;
3. Failure of at least two of the following agents at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated: dextromethorphan, benzonatate, guaifenesin;
4. Member is concurrently receiving appropriate therapy for the underlying cause of the cough (e.g., antihistamines, decongestants, bronchodilators, oral and/or inhaled corticosteroids, antibiotics);
5. Dose does not exceed the FDA-approved maximum recommended dose.

Approval duration: health plan-specific duration of approval, not to exceed 7 days

C. Other diagnoses/indications: Not applicable

II. Continued Therapy

Please note: for HIM-Arkansas – if a member's covered prescription pain medication requires a prior authorization, then the prior authorization shall not be denied if the member has a terminal illness.

A. Cancer, Sickle Cell, or Palliative Care Pain (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed health plan's approved quantity limit.

Approval duration: 12 months

B. All Other Indications in Section I (must meet all)**:**

1. Continued therapy for cough, or non-cancer, non-sickle cell or non-palliative care pain will not be authorized as the underlying causes of cough and pain must be treated with appropriate therapy.

C. Other diagnoses/indications: Not applicable

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
MAOI: monoamine oxidase inhibitors
NSAIDs: non-steroidal anti-inflammatory drugs
REMS: Risk Evaluation and Mitigation Strategy

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
acetaminophen (Tylenol®)	**Analgesia** Weight-based pediatric dosing 10 – 15 mg/kg/dose PO Q4 – 6 hr PRN	75 mg/kg/day not to exceed 4 g/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Age 6 to 11 years 325 mg PO Q4 – 6 hr PRN Age 12 years or older Immediate-release: 650 mg PO Q4 – 6 hr PRN or 1000 mg PO Q6 hr PRN Extended-release: 1300 mg PO Q8 hr PRN	
carbamazepine (Tegretol®)	**Neuropathic pain*** Initial: 50 – 100 mg PO BID Maintenance: 100 – 200 mg PO Q4 – 6 hr	1,200 mg/day
cyclobenzaprine (Fexmid®)	**Muscle spasm** Age 15 years or older 5 – 10 mg PO TID	30 mg/day
duloxetine (Cymbalta®)	**Chronic musculoskeletal pain** 30 mg PO QD for 1 week, then 60 mg PO QD	60 mg/day
gabapentin (Neurontin®)	**Neuropathic pain*** 1,200 – 3,600 mg/day PO in 3 divided doses	3,600 mg/day
ibuprofen (Advil®, Motrin®)	**Analgesia** Age 6 months to less than 12 years 4 – 10 mg/kg/dose PO Q6 – 8 hr PRN Age 12 to 17 years 400 mg PO Q4 – 6 hr PRN	40 mg/kg/day not to exceed 2,400 mg/day
oxycodone (Roxicodone®, OxyContin®)	**Moderate-to-severe pain** (immediate-release tablets) 0.1 – 0.2 mg/kg/dose (moderate pain) or 0.2 mg/kg/dose (severe pain) PO **Severe pain** (extended-release tablets) Age 11 months or older Initial dose PO based on conversion from current opioid regimen dose	N/A
morphine sulfate immediate-release	**Acute pain** Age 6 months or younger 0.08 – 0.1 mg/kg/dose PO Q3 – 4 hr Age greater than 6 months Weight < 50 kg: 0.2 – 0.5 mg/kg/dose PO Q3 – 4 hr PRN Weight ≥ 50 kg: 15 – 20 mg/kg PO Q3 – 4 hr PRN	N/A

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
dextromethorphan (Delsym®, Robitussin®)	**Cough (suppressant)** Age 4 to 6 years (syrup) Immediate-release: 2.5 – 7.5 mg PO Q4 – 8 hr PRN Extended-release: 15 mg PO BID PRN Age 6 to less than 12 years Immediate-release: 5 – 10 mg PO Q4 hr PRN or 15 mg PO Q6 – 8 hr PRN Extended-release: 30 mg PO BID PRN Age 12 years or older Immediate-release: 10 – 20 mg PO Q4 hr PRN or 20 – 30 mg PO Q6 – 8 hr PRN	Age 4 to 6 years: 30 mg/day Age 6 to 12 years: 60 mg/day Age ≥ 12 years: 120 mg/day
guaifenesin (Mucinex®)	**Cough (expectorant)** Age 2 to less than 4 years Liquid: 50 – 100 mg PO Q4 hr PRN Age 4 to less than 6 years 50 – 100 mg PO Q4 hr PRN Age 6 to less than 12 years 100 – 200 mg PO Q4 hr PRN Age 12 years or older 200 – 400 mg PO Q4 hr PRN	Age 2 to < 6 years: 600 mg/day Age 6 to < 12 years: 1,200 mg/day Age ≥ 12 years: 2,400 mg/day
benzonatate (Tessalon Perles®)	**Cough** Age greater than 10 years 100 – 200 mg PO TID PRN	600 mg/day
albuterol nebulizer	**Bronchospasm** Age 2 to less than 12 years Weight 10 – 15 kg: 0.63 – 1.25 mg PO TID or QID PRN Weight > 15 kg: 0.63 – 2.5 mg PO TID or QID PRN Age 12 years or older 2.5 mg PO TID or QID PRN	Varies
albuterol metered dose inhaler (ProAir®, Proventil®, Ventolin®)	**Bronchospasm** 2 inhalations Q4 – 6 hr PRN	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
diphenhydramine (Benadryl®)	**Cough** Age 12 years or older 25 mg PO Q4 hr PRN	150 mg/day
oxymetazoline (Afrin® Nasal Spray)	**Nasal congestion** Age 6 years or older 2 – 3 sprays in each nostril BID for ≤ 3 days	Max 3 days use
phenylephrine (Afrin® Childrens)	**Nasal congestion** Age 2 to less than 6 years 0.125% solution: 2 – 3 sprays in each nostril for no more than Q4 hrs for ≤ 3 days Age 6 to less than 12 years 0.25% solution: 2 – 3 sprays in each nostril for no more than Q4 hrs for ≤ 3 days Age 12 years or greater 0.25% to 1% solution: 2 – 3 sprays in each nostril for no more than Q4 hrs for ≤ 3 days	Max 3 days use
phenylephrine (Sudafed PE® Childrens)	**Nasal congestion** Age 4 to less than 6 years 2.5 mg PO Q4 hr PRN for ≤ 7 days Age 6 to less than 12 years 5 mg PO Q4 hr PRN for ≤ 7 days Age 12 years or greater 10 mg PO Q4 hr PRN for ≤ 7 days	Age 4 to < 6 years: 15 mg/day Age 6 to < 12 years: 30 mg/day Age ≥ 12 years: 60 mg/day
Qvar® (beclomethasone)	**Asthma** Age 5 to 11 years 40 – 80 mcg inhaled BID Age 12 years or greater 40 – 320 mcg inhaled BID	Age 5 to 11 years: 80 mcg BID/day Age ≥ 12 years: 320 mcg BID/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Off-label*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): use in children younger than 12 years of age; postoperative management in children younger than 18 years of age following tonsillectomy and/or adenoidectomy; significant respiratory depression; acute or severe bronchial asthma in an unmonitored setting or in absence of resuscitative equipment; concurrent use of monoamine oxidase inhibitors (MAOIs) or use of MAOIs within the last 14 days; known

or suspected gastrointestinal obstruction, including paralytic ileus; hypersensitivity to the active ingredient.

- Boxed warning(s): risks of misuse, abuse, addiction, overdose, death; serious or life-threatening respiratory depression; accidental ingestion; neonatal opioid withdrawal syndrome; concomitant use or discontinuation of cytochrome P450 3A4 inducers, 3A4 inhibitors, or 2D6 inhibitors; concomitant use with benzodiazepines or other central nervous system depressants; Risk Evaluation and Mitigation Strategy (REMS); ultra-rapid metabolism of codeine or tramadol and other risk factors for life-threatening respiratory depression in children.

V. Dosage and Administration

There are various codeine-, tramadol-, and hydrocodone-containing medications commercially available. Please refer to the respective package inserts for dosing and administration.

VI. Product Availability

Please refer to the respective package inserts for product availability.

VII. References

1. Codeine Prescribing Information. Eatontown, NJ: West-Ward Pharmaceuticals Corp; December 2023. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=010905f9-3bcb-4b50-9fe8-a3ad0010f14c. Accessed January 18, 2024.
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3. Tussionex Prescribing Information. Smyrna, GA: UCB, Inc.; January 2017. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=af2caf33-e587-4d80-9523-44e1b565aae2. Accessed January 18, 2024.
4. Tuxarin ER Prescribing Information. Louisville, KY: MainPointe Pharmaceuticals, LLC; December 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/206323s008lbl.pdf. Accessed February 16, 2024
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: https://www.clinicalkey.com/pharmacology/login. Accessed February 8, 2024.
6. Food and Drug Administration. FDA Drug Safety Communication: FDA restricts use of prescription codeine pain and cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women. 2017. https://www.fda.gov/Drugs/DrugSafety/ucm549679.htm.
7. Food and Drug Administration. FDA Drug Safety Communication: FDA requires labeling changes for prescription opioid cough and cold medicines to limit their use to adults 18 years and older. 2018. https://www.fda.gov/Drugs/DrugSafety/ucm590435.htm.
8. Chang AB, Oppenheimer JJ, Weinberger MM, et al. Management of children with chronic wet cough and protracted bacterial bronchitis. Chest Journal. 2017;151(4):884-890.

9. Malesker MA, Callahan-Lyon P, Ireland B, Irwin RS. Pharmacologic and nonpharmacologic treatment for acute cough associated with the common cold. CHEST Journal. 2017;152(5):1021-1037.
10. World Health Organization (WHO). WHO guidelines on the pharmacological treatment of persisting pain in children with medical illnesses. 2012. Available at http://apps.who.int/iris/bitstream/10665/44540/1/9789241548120_Guidelines.pdf.
11. Dowell D, Ragan KR, Jones CM, Baldwin GT, and Chou R. CDC clinical practice guideline for prescribing opioids for pain – United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1-95.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2020 annual review: no significant changes; references reviewed and updated.	02.04.20	05.20
2Q 2021 annual review: no significant changes; for section III. Diagnoses/Indications for which coverage is NOT authorized, replaced "Not applicable" with template language for that section; references reviewed and updated.	03.01.21	05.21
2Q 2022 annual review: no significant changes; references reviewed and updated.	02.28.22	05.22
Template changes applied to continued therapy section.	10.03.22	
2Q 2023 annual review: no significant changes; references reviewed and updated.	02.03.23	05.23
2Q 2024 annual review: no significant changes; limitations of use added to FDA approved indications section; references reviewed and updated.	01.18.24	05.24

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,

contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.