

Clinical Policy: Age Limit Override for Codeine, Tramadol, Hydrocodone

Reference Number: ERX.NPA.67

Effective Date: 03.13.18

Last Review Date: 05.20

Line of Business: Commercial, 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 pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

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

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that codeine-, tramadol-, and hydrocodone-containing opioids are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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.*

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. Prescribed by or in consultation with an oncologist, hematologist, hospice provider, or pain specialist for cancer, palliative care, or sickle cell disease;
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: 7 days

C. Other diagnoses/indications: Not applicable

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
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

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.

Approval duration: Not applicable

C. Other diagnoses/indications: Not applicable

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

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

NSAIDs: non-steroidal anti-inflammatory drugs

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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Analgesic agents		
acetaminophen (Tylenol®)	Analgesia <u>Weight-based pediatric dosing</u> 10 – 15 mg/kg/dose PO Q4 – 6 hr PRN <u>Age 6 to 11 years</u> 325 mg PO Q4 – 6 hr PRN	75 mg/kg/day not to exceed 4 g/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	<u>Age 12 years or older</u> 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 <u>Age 15 years or older</u> 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 <u>Age 6 months to less than 12 years</u> 4 – 10 mg/kg/dose PO Q6 – 8 hr PRN <u>Age 12 to 17 years</u> 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) <u>Age 11 months or older</u> Initial dose PO based on conversion from current opioid regimen dose	N/A
morphine sulfate immediate-release	Acute pain <u>Age 6 months or younger</u> 0.08 – 0.1 mg/kg/dose PO Q3 – 4 hr <u>Age greater than 6 months</u> 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
Cough and cold agents		
dextromethorphan (Delsym®, Robitussin®)	Cough (suppressant) <u>Age 4 to 6 years (syrup)</u> Immediate-release: 2.5 – 7.5 mg PO Q4 – 8 hr PRN Extended-release: 15 mg PO BID PRN <u>Age 6 to less than 12 years</u> Immediate-release: 5 – 10 mg PO Q4 hr PRN or 15 mg PO Q6 – 8 hr PRN Extended-release: 30 mg PO BID PRN <u>Age 12 years or older</u> 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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
guaifenesin (Mucinex [®])	<p>Cough (expectorant) <u>Age 2 to less than 4 years</u> Liquid: 50 – 100 mg PO Q4 hr PRN</p> <p><u>Age 4 to less than 6 years</u> 50 – 100 mg PO Q4 hr PRN</p> <p><u>Age 6 to less than 12 years</u> 100 – 200 mg PO Q4 hr PRN</p> <p><u>Age 12 years or older</u> 200 – 400 mg PO Q4 hr PRN</p>	<p>Age 2 to < 6 years: 600 mg/day</p> <p>Age 6 to < 12 years: 1,200 mg/day</p> <p>Age ≥ 12 years: 2,400 mg/day</p>
benzonatate (Tessalon Perles [®])	<p>Cough <u>Age greater than 10 years</u> 100 – 200 mg PO TID PRN</p>	600 mg/day
albuterol nebulizer	<p>Bronchospasm <u>Age 2 to less than 12 years</u> 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</p> <p><u>Age 12 years or older</u> 2.5 mg PO TID or QID PRN</p>	Varies
albuterol metered dose inhaler (ProAir [®] , Proventil [®] , Ventolin [®])	<p>Bronchospasm 2 inhalations Q4 – 6 hr PRN</p>	Varies
diphenhydramine (Benadryl [®])	<p>Cough <u>Age 12 years or older</u> 25 mg PO Q4 hr PRN</p>	150 mg/day
oxymetazoline (Afrin [®] Nasal Spray)	<p>Nasal congestion <u>Age 6 years or older</u> 2 – 3 sprays in each nostril BID for ≤ 3 days</p>	Max 3 days use
phenylephrine (Afrin [®] Childrens)	<p>Nasal congestion <u>Age 2 to less than 6 years</u> 0.125% solution: 2 – 3 sprays in each nostril for no more than Q4 hrs for ≤ 3 days</p> <p><u>Age 6 to less than 12 years</u> 0.25% solution: 2 – 3 sprays in each nostril for no more than Q4 hrs for ≤ 3 days</p> <p><u>Age 12 years or greater</u> 0.25% to 1% solution: 2 – 3 sprays in each nostril for no more than Q4 hrs for ≤ 3 days</p>	Max 3 days use
phenylephrine (Sudafed PE [®] Childrens)	<p>Nasal congestion <u>Age 4 to less than 6 years</u> 2.5 mg PO Q4 hr PRN for ≤ 7 days</p> <p><u>Age 6 to less than 12 years</u> 5 mg PO Q4 hr PRN for ≤ 7 days</p> <p><u>Age 12 years or greater</u> 10 mg PO Q4 hr PRN for ≤ 7 days</p>	<p>Age 4 to < 6 years: 15 mg/day</p> <p>Age 6 to < 12 years: 30 mg/day</p> <p>Age ≥ 12 years: 60 mg/day</p>

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Qvar® (beclomethasone)	<p>Asthma</p> <p><u>Age 5 to 11 years</u> 40 – 80 mcg inhaled BID</p> <p><u>Age 12 years or greater</u> 40 – 320 mcg inhaled BID</p>	<p>Age 5 to 11 years: 80 mcg BID/day</p> <p>Age ≥ 12 years: 320 mcg BID/day</p>

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

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; October 2019. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=010905f9-3bcb-4b50-9fe8-a3ad0010f14c>. Accessed February 4, 2020.
2. Ultram Prescribing Information. Titusville, NJ: Janssen Pharmaceuticals, Inc.; October 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020281s045lbl.pdf. Accessed February 4, 2020.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed February 4, 2020.
4. 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. Available at: <https://www.fda.gov/Drugs/DrugSafety/ucm549679.htm>.
5. 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. Available at: <https://www.fda.gov/Drugs/DrugSafety/ucm590435.htm>.
6. 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.
7. 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.
8. 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. Accessed February 4, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	03.13.18	05.18
2Q 2019 annual review: no significant changes; initial approval duration for the treatment of cough is 7 days (vs. 14 days) based on 2Q18 Envolve P&T feedback which aimed for a shorter duration of opioid therapy and to align with the approval duration for the treatment of pain; references reviewed and updated.	02.27.19	05.19
2Q 2020 annual review: no significant changes; references reviewed and updated.	02.04.20	05.20

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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