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

Reference Number: PA.CP.PMN.138
Effective Date: 03.13.18
Last Review Date: 04.17.19

Revision Log

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;
- Tramadol-containing medications are not indicated for pain in patients younger than age 18 years (use is contraindicated 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, including discomfort associated with acute painful musculoskeletal conditions and management of the symptom complex of tension (or muscle contraction) headache.

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.

It is the policy of health plans affiliated with PA Health & Wellness® that opioids are **medically necessary** for the following reasons:

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 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 contraindicated or clinically significant adverse effects are experienced;
   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 contraindicated or clinically significant adverse effects are experienced;
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 - 5 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 contraindicated or clinically significant adverse effects are experienced: 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: 5 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 PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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)**:**
Continued therapy for cough, or non-cancer, -sickle cell or -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 (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53**.**

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 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 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	75 mg/kg/day not to exceed 4 g/day
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)	N/A

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Age 11 months or older Initial dose PO based on conversion from current opioid regimen dose	
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
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	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	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	
albuterol metered dose inhaler (ProAir®, Proventil®, Ventolin®)	**Bronchospasm** 2 inhalations Q4 – 6 hr PRN	Varies
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	Age 5 to 11 years: 80 mcg BID/day Age ≥ 12 years: 320 mcg BID/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	40 – 320 mcg inhaled BID	

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.

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. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/. Accessed February 27, 2019.
2. 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 breastfeeeding women. 2017. https://www.fda.gov/Drugs/DrugSafety/ucm549679.htm.
3. 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.
4. 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.
5. 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.
6. 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 27, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	03.13.18	04.18.18
2Q 2019 annual review: Updated the initial approval duration for cough to 5 days to align with the treatment duration for pain. References reviewed and updated.	04.17.19	