SmartPA Criteria Proposal

Drug/Drug Class:	Opioids – Short-Acting Combinations Clinical Edit
First Implementation Date:	February 8, 2012
Revised Date:	July 15, 2021
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: Ensure safe, appropriate utilization and control of short-acting opioid combinations

Why Issue Selected: Short-acting opioid combination agents contain both a short-acting opioid (such as hydrocodone, oxycodone, or codeine) as well as another non-opioid analgesic (typically acetaminophen, aspirin, or ibuprofen). These combination agents are indicated for short-term relief of moderate to severe pain on an "as needed" basis. Although highly effective for pain control, the opioid component has the potential for harm from adverse drug events and/or overdose. When maximum dosage limits are exceeded, the non-opioid components can cause serious toxicity to the patient in the form of liver or kidney injury. Use of opioid combination products with benzodiazepines or in conjunction with various other prescription or over-the-counter (OTC) drugs significantly increases the risk of harm from these products.

In March 2016, the Centers for Disease Control and Prevention (CDC) released their Guideline for Prescribing Opioids for Chronic Pain. Although these guidelines focus on managing chronic pain, they emphasize the need for prescribers to be more judicious in the initiation, continuation, selection, and monitoring of opioids and other medications for acute pain. As part of the efforts to protect participants from the possible adverse effects of opioid medications and subsequent diversion or misuse of opioid medications, MO HealthNet Division will continue to clinically edit the use of these controlled substances. Limiting or reducing "morphine equivalent doses" helps avoid harmful effects of opioids and promotes patient safety. Opioid daily doses above 50 MME (morphine milligram equivalents) increase the risk of overdose by at least double. Other preventative activities include limiting prescription amounts and frequency of dispensing.

In a Safety Announcement dated April 20, 2017, the Food and Drug Administration (FDA) advised that it is restricting the use of codeine and tramadol medicines in children. Codeine is approved to treat pain and cough, and tramadol is approved to treat pain. These medicines carry serious risks, including slowed or difficult breathing and death, which appear to impose a greater risk in children younger than 12 years, and hence codeine and tramadol containing agents should not be used in these children. These medicines should also be limited in some older children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults. The FDA is also recommending against the use of codeine and tramadol medicines in breastfeeding mothers due to possible harm to their infants.

In another Safety Announcement date January 11, 2018, the FDA advised that it is restricting the use of prescription cough and cold medicines containing codeine or hydrocodone to adults 18 years and older. The FDA determined that the risks of slowed or difficult breathing, misuse, addiction, overdose, and death with these cold and cough medicines outweighed the benefits in patients younger than 18 years of age.

Type of Criteria:	☒ **Increased risk of ADE**	☐ **Preferred Drug List**
	☒ **Appropriate Indications**	☒ **Clinical Edit**
Data Sources:	☐ **Only Administrative Databases**	☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Short-acting opioid combinations
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Documented diagnosis of cancer in the past 6 months **OR**
- Documented diagnosis of sickle cell disease in the past 6 months **OR**
- Participant currently enrolled in Hospice care or receiving palliative care in the past year **OR**
- Claim does not exceed approved dosage limitations:
  - Participant aged < 18 years: see Appendix B **OR**
  - Participant aged ≥ 18 years: see Appendix A **OR**
  - Participant demonstrates compliance without dose escalation to prescribed therapy over the current MME threshold
- If no prior history of opioid therapy in the past 90 days:
  - Claim is for ≤ 7 days supply **AND**
  - Claim is for ≤ 50 MME per day **or maximum dose per day per package labeling, whichever is lower**
- If claim plus history equals > 60 days of short acting opioid therapy in the past 90 days: documented diagnosis of chronic non-malignant pain (CNMP) in the past 6 months required
- Approval based upon clinical consultant review and/or receipt of signed Opioid Attestation Form from prescriber

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Documented opioid dependence therapy in the past 45 days
- Participant aged < 18 years and claim is for an opioid cough or cold therapy or other agent not approved for pediatric use
- Participant aged < 12 years and claim is for a codeine containing agent
- Prior history of any short acting opioid in the past 3 days
- Denial criteria contained within the High Risk Therapies Clinical Edit: Claim is for an opioid (excluding buprenorphine tablets and buprenorphine/naloxone combinations) and:
  - Participant has history of > 3 days of select oral benzodiazepine therapy (alprazolam, chlordiazepoxide, clonazepam, clorazepate, diazepam, lorazepam, and oxazepam) in the past 60 days **AND**
  - Participant lacks history of at least 1 claim for an opioid emergency reversal agent in the past 2 years

Required Documentation

Laboratory Results:		Progress Notes:	
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

Default Approval Period

7 days

Appendix A – Adult Dose Chart

Drug Description	Max Units Per Day
APADAZ 4.08-325 MG TABLET	12 TABLETS
APADAZ 6.12-325 MG TABLET	12 TABLETS
APADAZ 8.16-325 MG TABLET	12 TABLETS
BUTALBITAL 50 MG / CAFFEINE 40 MG / CODEINE PHOSPHATE 30 MG / ASA 325 MG	6 TABLETS
BUTALBITAL 50 MG / CAFFEINE 40 MG / APAP 300 MG / CODEINE 30 MG	6 TABLETS
BUTALBITAL 50 MG / CAFFEINE 40 MG / CODEINE PHOSPHATE 30 MG / APAP 325 MG	6 TABLETS
CARISOPRODOL 200 MG / CODEINE PHOSPHATE 16 MG / ASA 325 MG	8 TABLETS
CODEINE 12 MG / APAP 120 MG PER 5 ML	150 ML
CODEINE PHOSPHATE 10 MG / PROMETHAZINE HCL 6.25 MG PER 5 ML	30 ML
CODEINE PHOSPHATE 10 MG/PROMETHAZINE HCL 6.25MG/PHENYLEPHRINE 5MG/5ML	30 ML
CODEINE PHOSPHATE 15 MG / APAP 300 MG	13 TABLETS
CODEINE PHOSPHATE 30 MG / APAP 300 MG	12 TABLETS
CODEINE PHOSPHATE 60 MG / APAP 300 MG	6 TABLETS
DIHYDROCODEINE 16 MG / CAFFEINE 30 MG / ASA 356.4 MG	8 TABLETS
DIHYDROCODEINE 16MG / CAFFEINE 30MG / APAP 320.5MG	10 TABLETS
DIHYDROCODEINE 16MG / CAFFEINE 30MG / APAP 325MG	10 TABLETS
GUAIFENESIN/HYDROCODONE 200-2.5/5 SOLUTION ORAL	180 ML
HYDROCODONE 10 MG / APAP 300 MG	9 TABLETS
HYDROCODONE 10 MG / APAP 300 MG PER 15 ML	135 ML
HYDROCODONE 10 MG / APAP 325 MG	9 TABLETS
HYDROCODONE 10 MG / APAP 325 MG PER 15 ML	135 ML
HYDROCODONE 10 MG / IBUPROFEN 200 MG	5 TABLETS
HYDROCODONE 2.5 MG / APAP 108 MG PER 5 ML	180 ML
HYDROCODONE 2.5 MG / APAP 325 MG	12 TABLETS
HYDROCODONE 5 MG / APAP 300 MG	13 TABLETS
HYDROCODONE 5 MG / APAP 325 MG	12 TABLETS
HYDROCODONE 5 MG / HOMATROPINE 1.5 MG PER 5 ML	30 ML
HYDROCODONE 5 MG / IBUPROFEN 200 MG	5 TABLETS
HYDROCODONE 7.5 MG / APAP 300 MG	12 TABLETS
HYDROCODONE 7.5 MG / APAP 325 MG	12 TABLETS
HYDROCODONE 7.5 MG / APAP 325 MG PER 15 ML	180 ML
HYDROCODONE 7.5 MG / IBUPROFEN 200 MG	5 TABLETS

HYDROCODONE BITARTRATE 10 MG/CHLORPHENIRAMINE POLISTIREX 8 MG PER 5 ML	10 ML
OXYCODONE 10 MG / APAP 300 MG	6 TABLETS
OXYCODONE 10 MG / APAP 325 MG	6 TABLETS
OXYCODONE 2.5 MG/ APAP 300 MG	12 TABLETS
OXYCODONE 2.5 MG / APAP 325 MG	12 TABLETS
OXYCODONE 4.83 MG / ASA 325 MG	12 TABLETS
OXYCODONE 5 MG / APAP 300 MG	12 TABLETS
OXYCODONE 5 MG / APAP 325 MG	12 TABLETS
OXYCODONE 5 MG / APAP 325 MG PER 5 ML	61 ML
OXYCODONE 5 MG / IBUPROFEN 400 MG	4 TABLETS
OXYCODONE 7.5 MG / APAP 300 MG	8 TABLETS
OXYCODONE 7.5 MG / APAP 325 MG	8 TABLETS
PENTAZOCINE HYDROCHLORIDE 50 MG / NALOXONE 0.5 MG TABLET	12 TABLETS
VITUZ 5 MG/4 MG/ 5 ML SOLUTION	20 ML

Appendix B – Pediatric Dose Chart

Drug Description	Max Units per Day
CODEINE 12 MG / APAP 120 MG PER 5 ML	150 ML
CODEINE PHOSPHATE 15 MG / APAP 300 MG	13 TABLETS
CODEINE PHOSPHATE 30 MG / APAP 300 MG	12 TABLETS
CODEINE PHOSPHATE 60 MG / APAP 300 MG	6 TABLETS
HYDROCODONE 10 MG / APAP 300 MG	9 TABLETS
HYDROCODONE 10 MG / APAP 300 MG PER 15 ML	135 ML
HYDROCODONE 10 MG / APAP 325 MG	9 TABLETS
HYDROCODONE 10 MG / APAP 325 MG PER 15 ML	135 ML
HYDROCODONE 10 MG / IBUPROFEN 200 MG	5 TABLETS
HYDROCODONE 2.5 MG / APAP 108 MG PER 5 ML	180 ML
HYDROCODONE 2.5 MG / APAP 325 MG	12 TABLETS
HYDROCODONE 5 MG / APAP 300 MG	13 TABLETS
HYDROCODONE 5 MG / APAP 325 MG	12 TABLETS
HYDROCODONE 5 MG / IBUPROFEN 200 MG	5 TABLETS
HYDROCODONE 7.5 MG / APAP 300 MG	12 TABLETS
HYDROCODONE 7.5 MG / APAP 325 MG	12 TABLETS
HYDROCODONE 7.5 MG / APAP 325 MG PER 15 ML	180 ML
HYDROCODONE 7.5 MG / IBUPROFEN 200 MG	5 TABLETS
OXYCODONE 10 MG / APAP 300 MG	6 TABLETS
OXYCODONE 10 MG / APAP 325 MG	6 TABLETS
OXYCODONE 2.5 MG/ APAP 300 MG	12 TABLETS
OXYCODONE 2.5 MG / APAP 325 MG	12 TABLETS
OXYCODONE 5 MG / APAP 300 MG	12 TABLETS
OXYCODONE 5 MG / APAP 325 MG	12 TABLETS
OXYCODONE 5 MG / APAP 325 MG PER 5 ML	60 ML
OXYCODONE 5 MG / IBUPROFEN 400 MG	4 TABLETS
OXYCODONE 7.5 MG / APAP 300 MG	8 TABLETS
OXYCODONE 7.5 MG / APAP 325 MG	8 TABLETS
PENTAZOCINE HYDROCHLORIDE 50 MG / NALOXONE 0.5 MG TABLET	12 TABLETS

References

- Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1
- U.S. Food and Drug Administration. Drug Safety Communications: FDA requires labeling changes for prescription opioid cough and cold medicines to limit their use to adults 18 years and older. https://www.fda.gov/files/drugs/published/Drug-Safety-Communication--Opioid-Cough-and-Cold-Meds.pdf. Accessed November 10, 2020.
- U.S. Food and Drug Administration. Drug Safety Communications: FDA restricts use of prescription codeine pain and cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women. https://www.fda.gov/media/104268/download. Accessed November 10, 2020.
- Oregon Health Authority – Opioid Conversion Calculator. https://www.oregonpainguidance.org/opioidmedcalculator/. Accessed November 10, 2020.
- Facts and Comparisons. Opioid Analgesic Combinations. Accessed November 10, 2020.