SmartPA Criteria Proposal

Drug/Drug Class:	Opioids – Short-Acting Clinical Edit
First Implementation Date:	February 8, 2012
Revised Date:	April 7, 2022
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 opioids

Why Issue Selected: Short-acting opioids are indicated for short-term relief of moderate to severe pain on an "as needed" basis. These medications are often used in conjunction with a long-acting opioid to help relieve breakthrough pain. Although highly effective for pain control, these substances carry with them the potential for harm from adverse drug events and/or overdose. Opioid drugs also have substantial misuse liability and are often implicated among persons who have developed a substance misuse disorder. Concomitant use of benzodiazepines significantly increases the risk of harm from opioids.

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 opioids
- 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 for a promethazine with codeine agent: Clinical consultant review for medical necessity OR**
- Claim is for methadone and participant has no prior history of methadone therapy in the past 90 days: Clinical Consultant Review required **AND**
- 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 day 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 OR**~~
- Approval based upon clinical consultant review ~~**and/or receipt of signed Opioid Attestation Form from prescriber**~~
- **Participant must also meet all approval criteria contained within the Morphine Milligram Equivalent Accumulation Clinical Edit**

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Documented opioid dependence therapy in the past 45 days
- **Documented Lybalvi 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 agent
- Prior history of any short acting opioid in the past 3 days **with a different prescribing provider**

- 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 **oral benzodiazepine therapy** in the past 60 days **OR**
  - **Participant has history of > 3 days of select sedative hypnotic therapy (eszopiclone, zaleplon, or zolpidem) in the past 60 days OR**
  - **Participant has history of > 3 days of gabapentinoid therapy (gabapentin or pregabalin) 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	**8 TABLETS**
APADAZ 6.12-325 MG TABLET	**8 TABLETS**
APADAZ 8.16-325 MG TABLET	**8 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
BUTORPHANOL TARTRATE 10 MG/ML NASAL SPRAY	0.5 ML
CARISOPRODOL 200 MG/CODEINE PHOSPHATE 16 MG/ASA 325 MG	8 TABLETS
CODEINE 12 MG/APAP 120 MG PER 5 ML	**90 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	**6 TABLETS**
CODEINE PHOSPHATE 30 MG/APAP 300 MG	**6 TABLETS**
CODEINE PHOSPHATE 60 MG/APAP 300 MG	6 TABLETS
CODEINE SULFATE 15 MG TABLET	**6 TABLETS**
CODEINE SULFATE 30 MG TABLET	**6 TABLETS**
CODEINE SULFATE 60 MG TABLET	6 TABLETS
DIHYDROCODEINE 16 MG/CAFFEINE 30 MG/ASA 356.4 MG	8 TABLETS
DIHYDROCODEINE 16 MG/CAFFEINE 30 MG/APAP 320.5 MG	10 TABLETS
DIHYDROCODEINE 16 MG/CAFFEINE 30 MG/APAP 325 MG	10 TABLETS
DSUVIA 30 MCG SL TAB	12 TABLETS
GUAIFENESIN/HYDROCODONE 200-2.5/5 SOLUTION	**60 ML**
HYDROCODONE 10 MG/APAP 300 MG	**8 TABLETS**
HYDROCODONE 10 MG/APAP 300 MG PER 15 ML	**90 ML**

HYDROCODONE 10 MG/APAP 325 MG	**8 TABLETS**
HYDROCODONE 10 MG/APAP 325 MG PER 15 ML	**90 ML**
HYDROCODONE 10 MG/IBUPROFEN 200 MG	5 TABLETS
HYDROCODONE 2.5 MG/APAP 108 MG PER 5 ML	**30 ML**
HYDROCODONE 2.5 MG/APAP 325 MG	**8 TABLETS**
HYDROCODONE 5 MG/APAP 300 MG	**8 TABLETS**
HYDROCODONE 5 MG/APAP 325 MG	**8 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	**8 TABLETS**
HYDROCODONE 7.5 MG/APAP 325 MG	**8 TABLETS**
HYDROCODONE 7.5 MG/APAP 325 MG PER 15 ML	**90 ML**
HYDROCODONE 7.5 MG/IBUPROFEN 200 MG	5 TABLETS
HYDROCODONE BITARTRATE 10 MG/CHLORPHENIRAMINE POLISTIREX 8 MG PER 5 ML	10 ML
HYDROMORPHONE 1 MG/ML AMPULE	22 ML
HYDROMORPHONE 2 MG/ML AMPULE	11 ML
HYDROMORPHONE 4 MG/ML AMPULE	5.5 ML
HYDROMORPHONE HYDOCHLORIDE 1 MG/ML SOL	22 ML
HYDROMORPHONE HYDROCHLORIDE 2 MG TABLET	**6 TABLETS**
HYDROMORPHONE HYDROCHLORIDE 3 MG RECTAL SUPP	4 SUPPOSITORIES
HYDROMORPHONE HYDROCHLORIDE 4 MG TABLET	5.5 TABLETS
HYDROMORPHONE HYDROCHLORIDE 8 MG TABLET	2.5 TABLETS
LEVORPHANOL 2 MG TABLET	**4 TABLETS**
LEVORPHANOL 3 MG TABLET	**4 TABLETS**
MEPERIDINE HYDROCHLORIDE 100 MG TABLET	6 TABLETS
MEPERIDINE HYDROCHLORIDE 50 MG TABLET	**6 TABLETS**
MEPERIDINE HYDROCHLORIDE 50 MG/5 ML ORAL SOLUTION	60 ML
METHADONE 5 MG/0.5 ML ORAL SYR	-
METHADONE HYDROCHLORIDE 10 MG TABLET	-
METHADONE HYDROCHLORIDE 10 MG/5 ML SOL	-
METHADONE HYDROCHLORIDE 10 MG/ML CONC SOL	-
METHADONE HYDROCHLORIDE 40 MG ODT	-
METHADONE HYDROCHLORIDE 5 MG TABLET	-
METHADONE HYDROCHLORIDE 5 MG/5 ML SOL	-
MORPHINE SULF 10MG/0.5ML SOLN	4.5 ML
MORPHINE SULFATE 10 MG RECTAL SUPPOSITORY	6 SUPPOSITORIES
MORPHINE SULFATE 10 MG/5 ML SOLUTION	45 ML
MORPHINE SULFATE 100 MG/5 ML SOLUTION	4.5 ML
MORPHINE SULFATE 15 MG IMMEDIATE-RELEASE TAB	6 TABLETS
MORPHINE SULFATE 20 MG RECTAL SUPPOSITORY	4 SUPPOSITORIES
MORPHINE SULFATE 20 MG/5 ML SOLUTION	22.5 ML
MORPHINE SULFATE 30 MG IMMEDIATE-RELEASE TAB	3 TABLETS
MORPHINE SULFATE 30 MG RECTAL SUPPOSITORY	3 SUPPOSITORIES
MORPHINE SULFATE 5 MG RECTAL SUPPOSITORY	6 SUPPOSITORIES
NALBUPHINE 10 MG/ML AMPUL	16 ML
NALBUPHINE 100 MG/10 ML VIAL	16 ML
NALBUPHINE 20 MG/ML AMPUL	8 ML
NALBUPHINE 200 MG/10 ML VIAL	8 ML
OXYCODONE 10 MG/APAP 300 MG	6 TABLETS
OXYCODONE 10 MG/APAP 325 MG	6 TABLETS
OXYCODONE 10 MG/0.5 ML ORAL SYR	3 ML
OXYCODONE 2.5 MG/APAP 300 MG	**6 TABLETS**
OXYCODONE 2.5 MG/APAP 325 MG	**6 TABLETS**

OXYCODONE 4.83 MG/ASA 325 MG	**6 TABLETS**
OXYCODONE 5 MG/APAP 300 MG	**6 TABLETS**
OXYCODONE 5 MG/APAP 325 MG	**6 TABLETS**
OXYCODONE 5 MG/APAP 325 MG PER 5 ML	**40 ML**
OXYCODONE 5 MG/IBUPROFEN 400 MG	4 TABLETS
OXYCODONE 7.5 MG/APAP 300 MG	**6 TABLETS**
OXYCODONE 7.5 MG/APAP 325 MG	**6 TABLETS**
OXYCODONE HYDROCHLORIDE 10 MG TABLET	6 TABLETS
OXYCODONE HYDROCHLORIDE 15 MG TABLET	4 TABLETS
OXYCODONE HYDROCHLORIDE 20 MG TABLET	3 TABLETS
OXYCODONE HYDROCHLORIDE 20 MG/ML ORAL SOL	3 ML
OXYCODONE HYDROCHLORIDE 30 MG TABLET	2 TABLETS
OXYCODONE HYDROCHLORIDE 5 MG CAPSULE	**6 CAPSULES**
OXYCODONE HYDROCHLORIDE 5 MG TABLET	**6 TABLETS**
OXYCODONE HYDROCHLORIDE 5 MG/5 ML ORAL SOL	60 ML
OXYCODONE HYDROCHLORIDE 7.5 MG TABLET	**6 TABLETS**
OXYMORPHONE HYDROCHLORIDE 10 MG TABLET	3 TABLETS
OXYMORPHONE HYDROCHLORIDE 5 MG TABLET	6 TABLETS
PENTAZOCINE HYDROCHLORIDE 50 MG/NALOXONE 0.5 MG TABLET	12 TABLETS
ROXYBOND 15 MG TABLET	4 TABLETS
ROXYBOND 30 MG TABLET	2 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	**90 ML**
CODEINE PHOSPHATE 15 MG / APAP 300 MG	**6 TABLETS**
CODEINE PHOSPHATE 30 MG / APAP 300 MG	**6 TABLETS**
CODEINE PHOSPHATE 60 MG / APAP 300 MG	6 TABLETS
CODEINE SULFATE 15 MG ORAL TABLET	**6 TABLETS**
CODEINE SULFATE 30 MG ORAL TABLET	**6 TABLETS**
CODEINE SULFATE 60 MG ORAL TABLET	6 TABLETS
HYDROCODONE 10 MG / APAP 300 MG	**8 TABLETS**
HYDROCODONE 10 MG / APAP 300 MG PER 15 ML	**90 ML**
HYDROCODONE 10 MG / APAP 325 MG	**8 TABLETS**
HYDROCODONE 10 MG / APAP 325 MG PER 15 ML	**90 ML**
HYDROCODONE 10 MG / IBUPROFEN 200 MG	5 TABLETS
HYDROCODONE 2.5 MG / APAP 108 MG PER 5 ML	**30 ML**
HYDROCODONE 2.5 MG / APAP 325 MG	**8 TABLETS**
HYDROCODONE 5 MG / APAP 300 MG	**8 TABLETS**
HYDROCODONE 5 MG / APAP 325 MG	**8 TABLETS**
HYDROCODONE 5 MG / IBUPROFEN 200 MG	5 TABLETS
HYDROCODONE 7.5 MG / APAP 300 MG	**8 TABLETS**
HYDROCODONE 7.5 MG / APAP 325 MG	**8 TABLETS**
HYDROCODONE 7.5 MG / APAP 325 MG PER 15 ML	**90 ML**
HYDROCODONE 7.5 MG / IBUPROFEN 200 MG	5 TABLETS
HYDROMORPHONE 1 MG/ML AMPULE	12 ML
HYDROMORPHONE 2 MG/ML AMPULE	6 ML
HYDROMORPHONE 4 MG/ML AMPULE	3 ML
HYDROMORPHONE HYDOCHLORIDE 1 MG/ML SOLUTION	12 ML
HYDROMORPHONE HYDROCHLORIDE 2 MG TABLET	6 TABLETS

MORPHINE SULFATE 10 MG/0.5 ML SOLN	3 ML
MORPHINE SULFATE 10 MG RECTAL SUPPOSITORY	6 SUPPOSITORIES
MORPHINE SULFATE 10 MG/5 ML SOLUTION	30 ML
MORPHINE SULFATE 100 MG/5 ML SOLUTION	4 ML
MORPHINE SULFATE 15 MG IMMEDIATE-RELEASE TAB	2 TABLETS
MORPHINE SULFATE 20 MG/5 ML SOLUTION	15 ML
MORPHINE SULFATE 5 MG RECTAL SUPPOSITORY	6 SUPPOSITORIES
OXYCODONE 10 MG / APAP 300 MG	6 TABLETS
OXYCODONE 10 MG / APAP 325 MG	6 TABLETS
OXYCODONE 10 MG/0.5 ML ORAL SYR	1.5 ML
OXYCODONE 2.5 MG/APAP 300 MG	**6 TABLETS**
OXYCODONE 2.5 MG / APAP 325 MG	**6 TABLETS**
OXYCODONE 5 MG / APAP 300 MG	**6 TABLETS**
OXYCODONE 5 MG / APAP 325 MG	**6 TABLETS**
OXYCODONE 5 MG / APAP 325 MG PER 5 ML	**40 ML**
OXYCODONE 5 MG / IBUPROFEN 400 MG	4 TABLETS
OXYCODONE 7.5 MG / APAP 300 MG	**6 TABLETS**
OXYCODONE 7.5 MG / APAP 325 MG	**6 TABLETS**
OXYCODONE HYDROCHLORIDE 10 MG ORAL TABLET	3 TABLETS
OXYCODONE HYDROCHLORIDE 15 MG ORAL TABLET	2 TABLETS
OXYCODONE HYDROCHLORIDE 20 MG/ML ORAL SOL	1.5 ML
OXYCODONE HYDROCHLORIDE 5 MG ORAL CAPSULE	6 CAPSULES
OXYCODONE HYDROCHLORIDE 5 MG ORAL TABLET	6 TABLETS
OXYCODONE HYDROCHLORIDE 5 MG/5 ML ORAL SOL	30 ML
OXYCODONE HYDROCHLORIDE 7.5 MG ORAL TABLET	4 TABLETS
PENTAZOCINE HYDROCHLORIDE 50 MG / NALOXONE 0.5 MG TABLET	12 TABLETS
ROXYBOND 15 MG ORAL TAB	2 TABLETS
ROXYBOND 30 MG ORAL TAB	1 TABLET

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
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- Facts and Comparisons. Opioid Analgesics. Accessed November 10, 2021.