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OPIOID DRUGS

Benzhydrocodone-acetaminophen (Apadaz*) Buprenorphine (Belbuca) Buprenorphine (Buprenex) Buprenorphine patch (Butrans) Butorphanol Butorphanol (Stadolol) Butorphanol powder Celecoxib-tramadol (Seglentis) Codeine Codeine-acetaminophen Codeine powder Dihydrocodeine-caffeine-acetaminophen (Trezix) Dihydrocodeine-caffeine-acetaminophen* (Dvorah*) Fentanyl Fentanyl patch (Duragesic patch) Hydrocodone-acetaminophen Hydrocodone-acetaminophen solution 10-325mg* Hydrocodone-ibuprofen	Hydrocodone-acetaminophen Hydrocodone-acetaminophen solution 10-325mg* Hydrocodone-ibuprofen Hydrocodone ER (Hysingla ER, Zohydro ER) Hydrocodone powder Hydromorphone Hydromorphone IR (Dilaudid IR) Hydromorphone ER (Exalgo) Hydromorphone powder Levorphanol* Levorphanol powder Meperidine (Demerol) Meperidine powder Morphine Morphine IR Morphine powder Morphine sulfate ER (Arymo ER, Avinza, Kadian, MorphaBond, MS Contin) Morphine sulfate/naltrexone ER (Embeda)	Nalbuphine Oxycodone-acetaminophen Oxycodone-acetaminophen* (Nalocet*, Primlev*, Prolate*) Oxycodone-aspirin Oxycodone-ibuprofen Oxycodone ER (OxyContin, Xtampza ER) Oxycodone IR Oxycodone powder Oxymorphone IR (Opana IR) Oxymorphone ER (Opana ER) Oxymorphone powder Pentazocine-Naloxone Tapentadol IR (Nucynta IR) Tapentadol ER (Nucynta ER) Tramadol IR (Qdolo, Ultram) Tramadol-acetaminophen Tramadol ER (Conzip*, Ultram)

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RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Opioid drugs are medications that are used in the management of pain.

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, opioids should be reserved for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.

- **Maximum daily limit of any combination of opioid medications without a PA is 90 MME/day.**
- **Maximum daily limit of any combination of opioid medications with a PA is 200 MME/day for patients age 18 and older or 90 MME/day for patients age 17 and under.**

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- **There is no maximum daily limit for patients with pain associated with anesthesia, cancer, pain associated with sickle cell disease, or treatment associated with hospice, palliative, or end-of-life care.**

Regulatory Status

FDA-approved indications:

1. Opioid drugs are indicated for the management of pain.
2. Butorphanol Tartrate Injection: as a preoperative or pre-anesthetic medication, as a supplement to balanced anesthesia, for the relief of pain during labor, and for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
3. Demerol (meperidine) Injection: for preoperative medication, support of anesthesia, for obstetrical analgesia, and for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate

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4. Fentanyl Injection: analgesic action of short duration during the anesthetic periods, premedication, induction and maintenance, and in the immediate postoperative period (recovery room) as the need arises; use as an opioid analgesic supplement in general or regional anesthesia; administration with a neuroleptic as an anesthetic premedication, for the induction of anesthesia and as an adjunct in the maintenance of general and regional anesthesia; use as an anesthetic agent with oxygen in selected high risk patients, such as those undergoing open heart surgery or certain complicated neurological or orthopedic procedures

Opioids have boxed warnings for the following:

- Respiratory depression is the chief hazard of opioid agonists, which if not immediately recognized and treated, may lead to respiratory arrest and death. Risk is increased in patients receiving concurrent CNS depressants (including alcohol), patients with chronic obstructive pulmonary disease, orthostatic hypotension, increased intracranial pressure, biliary tract diseases, and seizure disorders. To reduce the risk of respiratory depression, proper dosing, titration, and monitoring are essential.

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- All patients treated with opioids require careful monitoring for signs of abuse and addiction, since use of opioid analgesic products carries the risk of addiction even under appropriate medical use.
- Accidental ingestion of extended-release opioids, especially in children, can result in fatal opioid overdose.
- Prolonged use of opioid agonists during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening.
- Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.

The Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain recommends that when opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day

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or carefully justify a decision to titrate dosage to ≥90 MME/day. The extended-release opioid drug initial quantity limits are set to encompass the usual/starting dosage and frequency range recommendations in labeling without exceeding 90 MME per day (16).

CDC guidelines find that concurrent use of benzodiazepines and opioids might put patients at greater risk for potentially fatal overdose. Three studies of fatal overdose deaths found evidence of concurrent benzodiazepine use in 31%–61% of decedents (16). The FDA also states that benzodiazepines “are also commonly abused and misused, often together with opioid pain relievers and other medicines” (22).

The CDC Guideline for Prescribing Opioids for Chronic Pain states that when starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting opioids. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize

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other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids (16).

The American Pain Society Opioid Treatment Guidelines state that a reasonable definition for high dose opioid therapy is >200 mg daily of oral morphine (or equivalent). The Institute for Clinical Systems Improvement Chronic Pain Guideline states that among patients receiving opioids for non-malignant pain, the daily dose is strongly associated with opioid-related mortality. An average dose of 200 mg or more morphine (or equivalent) was associated with a nearly nine-fold increase in the risk of overdose relative to low doses (<20 mg of morphine or equivalent) (15-18).

FDA warns that opioids can interact with antidepressants and migraine medicines to cause a serious central nervous system reaction called serotonin syndrome, in which high levels of the chemical serotonin build up in the brain and cause toxicity (see Appendix 1 for list of drugs) (17).

Centers for Medicare and Medicaid Services have a chart that includes buprenorphine MME conversion factors (21).

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The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary for all opioid analgesics intended for outpatient use to ensure that the benefits of these drugs continue to outweigh the risks. The Opioid Analgesic REMS is a strategy to reduce the risk of abuse, misuse, addiction, overdose, and deaths due to prescription opioid analgesics. Prescribers should counsel patients and caregivers about the use of naloxone for opioid overdose and consider prescribing naloxone if clinically indicated (21).

Summary

Opioid drugs are medications that are indicated for the management of pain. In addition, Butorphanol, Demerol and fentanyl injections are also indicated for pre-operative anesthesia. Because of the risks of addiction, abuse, and misuse with opioids, the CDC Guidelines recommends patients should receive treatment that provides the greatest benefits relative to the risks associated with that treatment in order to optimize patient outcomes.

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of opioid

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drugs while maintaining optimal therapeutic outcomes.

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