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Section:	Prescription Drugs	**Effective Date:**	July 1, 2022
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	September 14, 2018
Subject:	Immediate Release Opioid Drugs	**Page:**	1 of 16

Last Review Date: June 16, 2022

Immediate Release Opioid Drugs

Description

Codeine, Demerol (meperidine) / Dilaudid IR (hydromorphone IR) / Levorphanol* / Morphine IR / Nucynta IR (tapentadol IR) / Opana IR (oxymorphone IR) / Oxycodone IR / Pentazocine-Naloxone / Qdolo (tramadol IR) / Stadol (butorphanol) / tramadol IR 100mg tablets* / Ultram (tramadol IR)

*Prior authorization for certain non-covered formulations applies only to formulary exceptions

Background
Codeine, Demerol (meperidine), Dilaudid IR (hydromorphone IR), Levorphanol, Morphine IR, Opana IR (oxymorphone IR), Oxycodone IR, and Nucynta IR (tapentadol IR) are Schedule II narcotics. Pentazocine-Naloxone, Stadol (butorphanol), and Qdolo/Ultram (tramadol IR) are Schedule IV narcotics. Immediate-release opioids are drugs that are prescribed for the treatment of acute or chronic pain where an opioid is appropriate (1-16).

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. Immediate-release opioids are indicated for the management of acute or chronic pain (1-16).

Limits have been placed on naïve opioid patients based on CDC recommendations. The plan has set limits to patients who are naïve to opioids to a 7 day Pre-PA Allowance for adults and a 3 day Pre-PA Allowance for pediatric patients for immediate release (IR) opioids.

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.

Regulatory Status
FDA-approved indications: Codeine, Hydromorphone IR, Levorphanol, Meperidine, Morphine sulfate IR, Oxycodone IR, Oxymorphone IR, Tapentadol IR, and Tramadol IR are opioid agonists. Pentazocine-Naloxone and Stadol are mixed opiate agonist-antagonists. They are all indicated for the relief of acute and chronic pain when an opioid is appropriate (1-16).

Immediate-release opioids have boxed warnings for the following (1-16):

- 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. In order to reduce the risk of respiratory depression, proper dosing, titration, and monitoring are essential.

- All patients treated with opioids require careful monitoring for signs of abuse and addiction, as the use of opioid analgesic products carries the risk of addiction even under appropriate medical use.

- Accidental ingestion of immediate-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.

Morphine sulfate and oxymorphone are contraindicated in patients with paralytic ileus (2-3).

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 or carefully justify a decision to titrate dosage to ≥ 90 MME/day. The initial quantity limits for the immediate-release opioid drugs are set to encompass the usual/starting dosage and frequency range recommendations in labeling without exceeding 90 MME per day (17).

The 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 pain, clinicians should prescribe immediate-release opioids instead of extended-release 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 other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids (17).

The CDC has a new Opioid Guideline App. It is designed to help providers apply the recommendations of the CDC’s Guideline for Prescribing Opioids for Chronic Pain into clinical practice by putting the entire guideline, tools, and resources in the palm of their hand. It can be accessed via this URL: https://www.cdc.gov/drugoverdose/prescribing/app.html.

The FDA warns that opioids can interact with antidepressants and migraine medications 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) (18).

The SPACE randomized clinical trial showed that treatment with opioids was not superior to treatment with non-opioid medications for improving pain-related function over 12 months. Results do not support initiation of opioid therapy for moderate to severe chronic back pain or osteoarthritis pain (of the hip or knee) (19).

The FDA is restricting the use of codeine and tramadol in children. These medications carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in this population (20).

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).

The safety and effectiveness of immediate-release opioids in patients less than 18 years of age have not been established. The safety and effectiveness of Pentazocine-Naloxone in patients less than 12 years of age have not been established (1-16).

Related policies
Abstral, Actiq, Butrans, Duragesic, Extended Release Opioid Drugs, Fentanyl Powder, Fentora, IR Opioid Combo Drugs, Methadone, Opioid Injectables, Opioid Powders, Suboxone Drug Class, Subsys

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Immediate-release opioids may be considered **medically necessary** in patients with acute or chronic pain and if the conditions indicated below are met.

Immediate-release opioids may be considered **investigational** in all other patients and for all other indications.

Prior-Approval Requirements

Prior authorization is not required if prescribed by an oncologist and/or the member has paid pharmacy claims for an oncology medication(s) in the past 6 months

Age

12 years of age or older: Codeine, Pentazocine-Naloxone, and Qdolo/Ultram (tramadol IR) **ONLY**
18 years of age or older: Formulary Exception opioids and Butorphanol **ONLY**
No age limit for all other opioids

Diagnoses

Demerol (meperidine) ONLY

Patient must have **ALL** of the following:

1. Moderate to Severe Acute Pain (short term)
    a. **Age 18 or older:** Patient requires extended treatment beyond 7 days for ongoing management of ACUTE pain
    b. **Age 17 or under:** Patient requires extended treatment beyond 3 days for ongoing management of ACUTE pain
    c. Prescriber agrees to discontinue therapy after 30 days

Codeine, Hydromorphone IR, Levorphanol, Morphine IR, Nucynta IR, Oxycodone IR, Oxymorphone IR, Pentazocine-Naloxone, Stadol, and Tramadol IR

Patient must have **ONE** of the following:

1. Moderate to Severe Acute Pain (short term)
    a. **Age 18 or older:** Patient requires extended treatment beyond 7 days for ongoing management of ACUTE pain
    b. **Age 17 or under:** Patient requires extended treatment beyond 3 days for ongoing management of ACUTE pain
    c. Prescriber agrees to discontinue therapy after 30 days

2. Moderate to Severe Chronic Pain
    a. Prescriber agrees to assess the benefits of pain control (i.e. Care Plan signs of abuse, severity of pain) after 3 months of therapy

AND ALL of the following for **ALL** indications and **ALL** medications:

a. Alternative treatment options have been ineffective, not tolerated or inadequate for controlling the pain (i.e., non-opioid analgesics and other treatment modalities)
b. Prescriber agrees to evaluate the patient's response to therapy before changing dose or adding additional opioid medications
c. Prescriber agrees to assess patient for signs and symptoms of serotonin syndrome

d. Prescriber agrees to participate in the Opioid Analgesic REMS program and to monitor for abuse, misuse, addiction, and overdose and discontinue if necessary (*https://opioidanalgesicrems.com*)
e. **NO** dual therapy with opioid addiction treatment or methadone
f. **NO** dual therapy with an anti-anxiety benzodiazepine(s)
    i. Alprazolam (Xanax)
    ii. Clonazepam (Klonopin)
    iii. Diazepam (Valium)
    iv. Lorazepam (Ativan)
    v. Oxazepam (Serax)
    vi. Chlordiazepoxide (Librium)
    vii. Clorazepate dipotassium (Tranxene)
g. **NO** cumulative morphine milligram equivalent (MME) over:
    (e.g.,https://www.mdcalc.com/morphine-milligram-equivalents-mme-calculator, https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf, https://www.cdc.gov/opioids/providers/prescribing/app.html)
    i. 200 MME/day for patients 18 years of age or older
    ii. 90 MME/day for patients 17 years of age or under

Prior – Approval *Renewal* Requirements

Prior authorization is not required if prescribed by an oncologist and/or the member has paid pharmacy claims for an oncology medication(s) in the past 6 months

Age

12 years of age or older: Codeine, Pentazocine-Naloxone, and Qdolo/Ultram (tramadol IR) **ONLY**
18 years of age or older: Formulary Exception opioids and Butorphanol **ONLY**
No age limit for all other opioids

Diagnosis

Codeine, Hydromorphone, Levorphanol, Morphine sulfate IR, Nucynta IR, Oxycodone IR, Oxymorphone IR, Pentazocine-Naloxone, Stadol, and Tramadol IR

Patient must have the following:

1. Moderate to Severe Chronic Pain

AND ALL of the following:

a. Prescriber agrees to assess the benefits of pain control (i.e., Care Plan signs of abuse, severity of pain) after 3 months of therapy
b. Prescriber agrees to evaluate the patient's response to therapy before changing dose or adding additional opioid medications
c. Prescriber agrees to assess patient for signs and symptoms of serotonin syndrome
d. Prescriber agrees to participate in the Opioid Analgesic REMS program and to monitor for abuse, misuse, addiction, and overdose and discontinue if necessary (*https://opioidanalgesicrems.com*)
e. **NO** dual therapy with opioid addiction treatment or methadone
f. **NO** dual therapy with an anti-anxiety benzodiazepine(s)
    i. Alprazolam (Xanax)
    ii. Clonazepam (Klonopin)
    iii. Diazepam (Valium)
    iv. Lorazepam (Ativan)
    v. Oxazepam (Serax)
    vi. Chlordiazepoxide (Librium)
    vii. Clorazepate dipotassium (Tranxene)
g. **NO** cumulative morphine milligram equivalent (MME) over:
    (e.g., https://www.mdcalc.com/morphine-milligram-equivalents-mme-calculator, https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf, https://www.cdc.gov/opioids/providers/prescribing/app.html)
    i. 200 MME/day for patients 18 years of age or older
    ii. 90 MME/day for patients 17 years of age or under

Policy Guidelines

Pre - PA Allowance

Prior authorization is not required if prescribed by an oncologist and/or the member has paid pharmacy claims for an oncology medication(s) in the past 6 months

Age

12 years of age or older: Codeine, Pentazocine-Naloxone, and Qdolo/Ultram (tramadol IR) **ONLY**
18 years of age or older: Butorphanol **ONLY**
No age limit for all other opioids

Quantity

- Patients age 18 years or older will be able to fill the Pre-PA Allowance after they have filled an initial 7 day supply of IR opioid therapy or if they have been on IR or ER opioid therapy in the last 180 days.

- Patients age 17 or under will require a PA after they have filled a 3 day supply of the Pre-PA Allowance in the last 180 days.
- Patients with opioid addiction treatment or methadone in the last 30 days will not be eligible for Pre-PA Allowance.
- **Maximum daily limit of any combination of opioid medications without a PA is 90 MME/day.**

Tablets & Suppositories ≤ 90 MME/day

Medication	Strength	Quantity Limit
Butorphanol	10 mg/mL nasal spray	0.34 mL per day (Max: 12 units per 90 days)
Meperidine	50mg, 100mg	1 unit per day (Max: 90 units per 90 days)
Hydromorphone	8mg	2 units per day (Max: 180 units per 90 days)
Oxycodone/Roxybond	30mg	
Tapentadol	100mg	
Morphine sulfate	30mg, 30mg supp	3 units per day (Max: 270 units per 90 days)
Oxycodone	20mg	
Oxymorphone	10mg	
Tapentadol	75mg	
Codeine	15mg, 30mg, 60mg	4 units per day (Max: 360 units per 90 days)
Hydromorphone	2mg, 4mg, 3mg supp	
Morphine sulfate	15mg, 5mg supp, 10mg supp, 20mg supp	
Oxycodone/Roxybond/ Oxaydo	5mg cap, 5mg tab, 7.5mg, 10mg, 15mg	
Oxymorphone	5mg	
Pentazocine/naloxone	50/0.5mg	
Tapentadol	50mg	
Tramadol	50mg	6 units per day (Max: 540 units per 90 days)

Maximum daily limit of any combination of opioid medications without a PA is 90 MME/day.

Solution ≤ 90 MME/day

Medication / Strength	Quantity Limit
Hydromorphone liquid 5mg/5mL (1mg/mL)	20 units per day (Max: 1800 mL per 90 days)
Meperidine oral soln 50mg/5mL	4 units per day (Max: 360 mL per 90 days)
Morphine sulfate oral soln 10mg/5mL	30 units per day (Max: 2700 mL per 90 days)
Oxycodone soln 5mg/5mL	
Morphine sulfate oral soln 20mg/5mL	22.5 units per day

	(Max: 2025 mL per 90 days)
Morphine sulfate (conc) oral soln 20mg/mL (100mg/5mL)	4.5 units per day (Max: 405 mL per 90 days)
Oxycodone oral concentrate 20mg/mL (100mg/5mL)	3 units per day (Max: 270 mL per 90 days)
Qdolo (tramadol IR) oral solution 5mg/mL	60 units per day (Max: 5400 mL per 90 days)

Maximum daily limit of any combination of opioid medications without a PA is 90 MME/day.

Prior - Approval Limits

Age

12 years of age or older: Codeine, Pentazocine-Naloxone, and Qdolo/Ultram (tramadol IR) **ONLY**
18 years of age or older: Butorphanol **ONLY**
No age limit for all other opioids

Quantity

- **Tramadol IR: Maximum daily dose limit of any combination should NOT exceed 400 mg/day.**
- **18 years of age or older**: Maximum daily limit of any combination of opioid medications with a PA is 200 MME/day.
- **17 years of age or under**: Maximum daily limit of any combination of opioid medications with a PA is 90 MME/day.

Tablets, Capsules, Nasal Spray, Injections
≤ 200 MME/day (age 18 and older) or ≤ 90 MME/day (age 17 or under)

Medication / Strength	Morphine Milligram Equivalent (MME) per unit
Butorphanol 10 mg/mL nasal spray ***Age 18 and older only**	175 MME (per mL)
Codeine tab 15mg	2.25 MME
Codeine tab 30mg	4.5 MME
Codeine tab 60mg	9 MME
Hydromorphone tab 2mg	8 MME
Hydromorphone tab 4mg	16 MME
Hydromorphone tab 8mg	32 MME
Hydromorphone supp 3mg	12 MME

Meperidine tab 50mg	5 MME
Meperidine tab 100mg	10 MME
***Meperidine is for acute pain only**	
Morphine sulfate tab 15mg	15 MME
Morphine sulfate tab 30mg	30 MME
Morphine sulfate supp 5mg	5 MME
Morphine sulfate supp 10mg	10 MME
Morphine sulfate supp 20mg	20 MME
Morphine sulfate supp 30mg	30 MME
Oxycodone cap 5mg	7.5 MME
Oxycodone/Roxybond/Oxaydo tab 5mg	7.5 MME
Oxaydo tab 7.5mg	11.25 MME
Oxycodone tab 10mg	15 MME
Oxycodone/Roxybond tab 15mg	22.5 MME
Oxycodone tab 20mg	30 MME
Oxycodone/Roxybond tab 30mg	45 MME
Oxymorphone tab 5mg	15 MME
Oxymorphone tab 10mg	30 MME
Pentazocine/naloxone tab 50/0.5mg	18.5 MME
Tapentadol tab 50mg	20 MME
Tapentadol tab 75mg	30 MME
Tapentadol tab 100mg	40 MME
Tramadol tab 50mg	5 MME

Solution
≤ 200 MME/day (age 18 and older) or ≤ 90 MME/day (age 17 or under)

Medication / Strength	Morphine Milligram Equivalent (MME) per unit
Hydromorphone liquid 5mg/5mL (1mg/mL)	4 MME (per mL)

Meperidine oral soln 50mg/5mL	1 MME (per mL)
***Meperidine is for acute pain only**	
Morphine sulfate oral soln 10mg/5 mL	2 MME (per mL)
Morphine sulfate oral soln 20mg/5 mL	4 MME (per mL)
Morphine sulfate (conc) oral soln 20mg/mL (100 mg/5 mL)	20 MME (per mL)
Oxycodone soln 5mg/5mL	1.5 MME (per mL)
Oxycodone oral concentrate 100mg/5mL (20mg/mL)	30 MME (per mL)
Qdolo (tramadol IR) oral soln 5mg/mL	0.5 MME (per mL)

Medication / Strength with Approved Formulary Exception Only (Age 18 and older only)	**Morphine Milligram Equivalent (MME) per unit**
Levorphanol tab 2 mg	22 MME
Levorphanol tab 3 mg	33 MME
Tramadol 100 mg	10 MME

Maximum daily limit of any combination should NOT exceed 400 mg/day.

Duration 1 month for acute pain
6 months for chronic pain

Prior – Approval *Renewal* Limits

Same as above
NO renewal for Acute Pain

Rationale

Summary
Immediate-release opioids are scheduled medications that are indicated for the management of acute or chronic pain where an opioid is appropriate (1-16).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of immediate-release opioids while maintaining optimal therapeutic outcomes.

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Policy History

Date	Action
September 2018	Addition to PA Merge of IR opioids from policy numbers 5.70.25, 5.70.33, 5.70.34, 5.70.35, 5.70.40, 5.70.59
October 2018	Addition of Opioid Analgesic REMS requirement
February 2019	Addition of Levorphanol 3mg tablets
March 2019	Annual review and reference update
May 2019	Changed Levorphanol 3mg tablets to approved with MFE only
June 2019	Annual review
December 2019	Annual review. Addition of requirement of no cumulative MME over 300. Addition of 3 day limit Pre-PA for patients age 17 or under. Age 17 or under now require PA for any fill greater than 3 days. Combined with Butorphanol criteria 5.70.20. Moved Levorphanol 2mg to MFE with PA only
February 2020	Addition of Tramadol IR tablet 100mg to MFE with PA only and reworded Pre-PA Allowance statements. Updated Opioid Analgesic REMS link
March 2020	Annual review
May 2020	Removed Butorphanol injection - moved to Opioid Injectables policy
June 2020	Annual review
November 2020	Addition of Qdolo (tramadol IR) oral solution
March 2021	Annual review and reference update
December 2021	Per FEP, decreased the requirement for adults that cumulative MME cannot exceed 200 MME/day from 300 MME/day. Removed requirements “no other opioid at PA limits” and “no dual therapy with other immediate release opioids” due to blanket MME. Added requirement “Prescriber agrees to evaluate patient’s response to therapy before changing dose or adding additional opioid medications.” Revised PA quantity charts to remove quantity limits and add MME per unit. Combined the adult and pediatric PA quantity charts. Added 400 mg/day PA quantity limit for tramadol IR to align with the PI max daily dose.

February 2022	Updated Pre-PA allowance with oncology step edit statement. Per FEP: added “Prescribers should counsel patients and caregivers about the use of naloxone for opioid overdose” under regulatory status, and added MME calculating links
March 2022	Annual review
June 2022	Annual review. Revised butorphanol MME to 175 MME per mL to match Rx Claim update. Per SME, addition to regulatory status that prescriber should consider prescribing naloxone if clinically indicated.

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.

Appendix 1 - List of Serotonergic Medications

Selective Serotonin Reuptake Inhibitors (SSRIs)

paroxetine	Paxil, Paxil CR, Pexeva, Brisdelle
fluvoxamine	Luvox, Luvox CR
fluoxetine	Prozac, Prozac Weekly, Sarafem, Selfemra, Symbyax
sertraline	Zoloft
citalopram	Celexa
escitalopram	Lexapro

Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)

venlafaxine	Effexor XR
desvenlafaxine	Pristiq, Khedezla
duloxetine	Cymbalta
milnacipran	Savella

Tricyclic Antidepressants (TCAs)

amitriptyline	No brand name currently marketed
desipramine	Norpramin
clomipramine	Anafranil
imipramine	Tofranil, Tofranil PM
nortriptyline	Pamelor, Aventyl
protriptyline	Vivactil
doxepin	Zonalon, Silenor
trimipramine	Surmontil

Monoamine Oxidase Inhibitors (MAOIs)

isocarboxazid	Marplan
phenelzine	Nardil
selegiline	Emsam, Eldepryl, Zelapar
tranylcypromine	Parnate

Other Psychiatric Medicines

amoxapine	No brand name currently marketed
maprotiline	No brand name currently marketed
nefazodone	No brand name currently marketed
trazodone	Oleptro
buspirone	No brand name currently marketed
vilazodone	Viibryd
mirtazapine	Remeron, Remeron Soltab
lithium	Lithobid

Migraine Medicines

almotriptan	Axert
frovatriptan	Frova
naratriptan	Amerge
rizatriptan	Maxalt, Maxalt-MLT
sumatriptan	Imitrex, Imitrex Statdose, Alsuma, Sumavel Dosepro, Zecuity, Treximet
zolmitriptan	Zomig, Zomig-ZMT

Antiemetics

ondansetron	Zofran, Zofran ODT, Zuplenz
granisetron	Kytril, Sancuso
dolasetron	Anzemet
palonosetron	Aloxi

Other Serotonergic Medicines

dextromethorphan	Bromfed-DM, Delsym, Mucinex DM, Nuedexta
linezolid	Zyvox
cyclobenzaprine	Amrix
methylene blue	
St. John’s wort	
tryptophan	