Opioids Immediate Release (IR) New To Therapy with Daily Quantity Limit Program Criteria

This program applies to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx formularies.

This is a FlexRx standard and GenRx standard program.

FDA APPROVED INDICATIONS AND DOSAGE[4-39]

Single Ingredient Agent(s)	Indication(s)
butorphanol[a] Nasal spray	Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
Codeine[a] Tablet	Management of mild to moderate pain, where treatment with an opioid is appropriate and for which alternative treatments are inadequate
Dilaudid (hydromorphone)[a] Tablet Liquid	Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
Levorphanol[a] Tablet	Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
Meperidine Tablet Solution	Management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
Dolophine, Methadose (methadone)[a] Tablet Soluble tablet Solution Concentrate	Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate
Morphine[a] Tablet Concentrate Solution	Management of acute and chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
Oxaydo, Roxybond, Roxicodone (oxycodone)[a] Capsule Tablet Solution Concentrate	Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
Opana (oxymorphone)[a]	Management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate

Tablet	
Nucynta (tapentadol) Tablet	Management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults and pediatric patients aged 6 years and older with a body weight of at least 40 kg.
Qdolo (tramadol) Oral solution	Management of pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate
Ultram[a], Tramadol Tablet	Management of pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate
Combination Ingredient Agent(s)	**Indication(s)**
Apadaz, Benzhydrocodone/ acetaminophen Tablet	Short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
Tylenol w/Codeine Acetaminophen/ codeine[a] Tablet Oral solution	Management of mild to moderate pain, where treatment with an opioid is appropriate and for which alternative treatments are inadequate
Fioricet w/Codeine (butalbital/ acetaminophen/ caffeine/codeine)[a] Capsule	Management of the symptom complex of tension (or muscle contraction) headache when non-opioid analgesic and alternative treatments are inadequate
Fiorinal w/Codeine (butalbital/aspirin/ caffeine/codeine)[a] Capsule	Management of the symptom complex of tension (or muscle contraction) headache when non-opioid analgesic and alternative treatments are inadequate
Trezix, Acetaminophen/ caffeine/ dihydrocodeine Capsule, tablet	Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
Hydrocodone/ Acetaminophen[a] Solution	Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
Lortab (hydrocodone/ acetaminophen) Solution	Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate

Norco (hydrocodone/ acetaminophen)[a] Tablet	Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
Hydrocodone/ Ibuprofen[a] Tablet	Short-term management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
Nalocet, Oxycodone/ Acetaminophen, Primlev, Prolate Tablet Solution	Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
Percocet (oxycodone/ acetaminophen)[a] Tablet	Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
oxycodone/ aspirin[a] Tablet	Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
Oxycodone/Ibuprofen Tablet	Management of short term (no more than 7 days) acute to moderate pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
pentazocine/ naloxone[a] Tablet	Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
Seglentis (celecoxib/tramadol) Tablet	Management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate
Ultracet (tramadol/ acetaminophen)[a] Tablet	Management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate

a – generic available

CLINICAL RATIONALE

The Centers for Disease Control and Prevention (CDC) guidelines define acute pain as pain with abrupt onset and caused by an injury or other process that is not ongoing. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.[1]

Use of tramadol or codeine containing products in pediatric patients has caused life-threatening respiratory depression, with some of the reported cases occurring post-tonsillectomy and/or adenoidectomy. Ultra-rapid metabolizers are at increased risk of life-threatening respiratory depression due to a CYP2D6 polymorphism. Use in children under 12 years of age is contraindicated for these products, and for those between the ages of 12 and 18 years when used for post-operative pain management following tonsillectomy and/or adenoidectomy.[3]

The CDC defines chronic pain as pain that continues or is expected to continue more than three months or past the time of normal tissue healing. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids. The FDA modified labeling of ER/LA opioids, indicating they should be reserved for management of severe, continuous pain requiring daily, around-the-clock, long term opioid treatment. The CDC indicates ER/LA opioids should be reserved for severe, continuous pain and should be considered only for patients who have received immediate-release opioids daily for at least 1 week. Assessment should be done to determine if continued opioid therapy is needed.[1]

The American Society of Interventional Pain Physicians (ASIPP) 2017 Guideline for Responsible, Safe, and Effective Prescription of Opioids for Chronic Non-Cancer Pain states that there is similar effectiveness for long and short-acting opioids, with increased adverse consequences of long-acting opioids. Long-acting agents should only be used in the management of severe, intractable pain.

The guidelines recommend the following for the treatment of chronic non-cancer pain:[2]

- Initiating therapy with an opioid:
    - Complete a comprehensive assessment and document comprehensive history, general medical condition, psychosocial history, psychiatric status, and substance use history
    - Screen for opioid abuse, utilize prescription drug monitoring programs (PDMPs), and utilize urine drug testing (UDT) to identify opioid abusers, reduce opioid abuse, and potentially reduce doctor shopping. Utilize at initiation of therapy and to monitor adherence
    - Establish appropriate physical and psychological diagnoses prior to initiating therapy
    - A pain management consultation, for non-pain physicians, if use of chronic opioids is planned or in patients where the total daily dose will exceed the recommended CDC morphine equivalent therapy
    - Establish medical necessity prior to initiation or maintenance of opioid therapy based on average, moderate, or severe (≥4 on a scale of 0-10) pain and/or disability
    - Establish treatment goals of opioid therapy with regard to pain relief and improvement in function
    - Obtain a robust agreement prior to initiating and maintaining opioid therapy. Agreements reduce over-use, misuse, abuse, and diversion
- Assessing improvement:
    - Assess improvement based on analgesia, activity, aberrant behavior, and adverse effects. Clinicians should document at least a 30% improvement in pain or disability without adverse consequences
    - Therapy must be started with short-acting opioids and should be maintained with lose doses
    - Evidence of effectiveness is similar for long-acting and short-acting opioids with increased prevalence of adverse consequences of long-acting opioids

    - Long-acting opioids in high doses are recommended only in specific circumstances with severe intractable pain that is not amenable to short-acting opioids or moderate doses of long-acting opioids
    - Low dose should be considered up to 40 MME, 41-90 MME should be considered moderate dose, and greater than 91 MME as high dose
    - Long-acting opioids should not be utilized for initial opioid therapy
    - Monitor adherence via UDT and PDMP to identify patients who are non-compliant or abusing prescription or illicit drugs
    - Chronic opioid therapy may be continued, with continuous adherence monitoring, and modified in conjunction with or after failure of other modalities of treatments.

The 2022 CDC guidelines for Prescribing Opioids for Pain recommend the following for prescribing opioids for acute, subacute, and chronic pain:[1]

- When to initiate or continue opioids for chronic pain:
    - Clinicians should maximize use of non-pharmacologic and non-opioid pharmacologic therapies prior to initiating opioid therapy as appropriate for the specific condition and patient
    - Clinicians should consider opioids only if expected benefits for both pain and function are anticipated to outweigh risks to the patients. Opioids should be combined with non-pharmacologic therapy and non-opioid pharmacologic therapy, as appropriate
    - Clinicians should establish treatment goals with all patients prior to starting opioid therapy for chronic pain. Goals should include realistic goals for pain and function, and how to discontinue therapy if benefits do not outweigh the risks. Clinicians should only continue therapy with opioids if there is clinically meaningful improvement in pain and function that outweigh the risks to patient safety
    - Clinicians should discuss the risks and realistic benefits of opioid therapy prior to starting and periodically during therapy
- Opioid selection, dosage, duration, follow-up, and discontinuation:
    - Clinicians should prescribe immediate release opioids instead of extended release/long acting opioids when starting opioid therapy for chronic pain
    - The lowest effective dose should be prescribed when opioids are started. Clinicians should use caution when prescribing opioids, should reassess evidence of benefits and risks when increasing doses to greater than or equal to 50 morphine milligram equivalents (MME)/day, and should avoid increasing doses to greater than or equal to 90 MME/day or carefully justify titrating to doses greater than or equal to 90 MME/day
    - Opioids for acute pain should be prescribed at the lowest effective dose of immediate release opioids and should be prescribed at a quantity no greater than necessary for the expected duration of pain. Three days or less will often be sufficient; more than seven days will rarely be needed
    - Benefits and risks should be evaluated within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalations. Benefits and risks of continued therapy should be evaluated every 3 months or more frequently
    - Clinicians should re-evaluate patients at higher risk for opioid use disorder (e.g., patients with mental health conditions or depression, patients with a history of substance abuse, history of overdose, taking more than 50 MME/day, or taking other central nervous system depressants with opioids) more frequently than every 3 months
- Assessing Risk and addressing Harms of Opioid use:
    - Clinicians should incorporate into the management plan strategies to mitigate risk, including offering naloxone when there is increased risk of

opioid overdose, such as history of overdose, history of substance abuse disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use
    - Patient's history of controlled substance use should be reviewed by the clinician using state prescription drug monitoring program (PDMP) data to determine if the patient is receiving opioid dosages or dangerous combinations that put the patient at high risk for overdose. PDMP data should be reviewed when starting opioid therapy for chronic pain and periodically during opioid therapy, ranging from every prescription to every 3 months
    - Clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription and illicit drugs
    - Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible

The CDC guideline for opioid prescribing note that patients with cancer, sickle cell disease, and patients receiving palliative or end of life care are exempt from these recommendations. The guidelines also states that although identification of an opioid use disorder can alter the expected benefits and risks of opioid therapy for pain, patients with co-occurring pain and substance use disorder require ongoing pain management that maximizes benefits relative to risks. Clinicians should continue to use non-pharmacologic and non-opioid pharmacologic pain treatments as appropriate and consider consulting a pain specialist as needed to provide optimal pain management.[1]

References

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Opioids IR New To Therapy (Includes IR, ER, and Oncology) with Daily Quantity Limit

OBJECTIVE
The program will check if a patient is new to opioid therapy as defined as having no prior opioid use in the past 120 days. If the patient is new to therapy, the patient will be restricted to <50 MME per day and ≤7 days of therapy. The program will allow for exceptions for uses beyond these limits based on program requirements. The program will also check for appropriate age for requests for products containing tramadol, dihydrocodeine, and codeine. Requests for these agents will be limited to patients 12 years of age and older, and patients 12 to 18 years will be restricted from use for post-operative pain management following a tonsillectomy and/or adenoidectomy. (program applies to all Multi-Source Codes [M, N, O, Y])

TARGET AGENT(S) FOR NEW TO THERAPY[b]

SINGLE INGREDIENT AGENT(S)				
Brand (generic)	**GPI**	**Daily Quantity Limit**	**Quantity Equaling <50 MME/day**	**Age Limit**
butorphanol[a]				
10 mg/mL nasal spray	65200020102050	0.25 mL	See note*	NA
Codeine				
15 mg tablet	65100020200305	6 tablets	22 tablets	≥18 years
30 mg tablet[a]	65100020200310	6 tablets	11 tablets	≥18 years
60 mg tablet	65100020200315	6 tablets	5 tablets	≥18 years
Dilaudid (hydromorphone)[a]				
2 mg tablet	65100035100310	6 tablets	5 tablets	NA
4 mg tablet	65100035100320	6 tablets	3 tablets	NA
8 mg tablet	65100035100330	6 tablets	1 tablet	NA
1 mg/mL liquid	65100035100920	48 mL	10 mL	NA
Levorphanol[a]				
2 mg tablet	65100040100305	4 tablets	2 tablets	NA
3 mg tablet	65100040100310	4 tablets	1 tablet	NA
Meperidine				
50 mg tablet	65100045100305	12 tablets	10 tablets	NA
50 mg/5 mL solution	65100045102060	60 mL	50 mL	NA
Dolophine (methadone)[a]				
5 mg tablet	65100050100305	3 tablets	3 tablets	NA
10 mg tablet	65100050100310	3 tablets	1 tablet	NA
Methadose, Methadone[a]				
40 mg soluble tablet	65100050107320	3 tablets	see note*	NA
5 mg/5 mL solution	65100050102010	30 mL	11 mL	NA
10 mg/5 mL solution	65100050102015	15 mL	6 mL	NA
10 mg/mL concentrate	65100050101310	3 mL	1 mL	NA
Morphine sulfate				

15 mg tablet[a]	65100055100310	12 tablets	3 tablets	NA
30 mg tablet[a]	65100055100315	6 tablets	1 tablet	NA
10 mg/5 mL solution	65100055102065	90 mL	25 mL	NA
20 mg/5 mL solution[a]	65100055102070	45 mL	12 mL	NA
20 mg/mL concentrate[a]	65100055102090	9 mL	2 mL	NA
Oxaydo, Roxybond, Roxicodone (oxycodone)				
5 mg capsule[a]	65100075100110	12 capsules	6 capsules	NA
5 mg tablet[a]	65100075100310	12 tablets	6 tablets	NA
5 mg tablet	6510007510A530	12 tablets	6 tablets	NA
7.5 mg tablet	65100075100315	6 tablets	4 tablets	NA
10 mg tablet[a]	65100075100320	6 tablets	3 tablets	NA
15 mg tablet[a]	65100075100325	6 tablets	2 tablets	NA
15 mg tablet	6510007510A540	6 tablets	2 tablets	NA
20 mg tablet[a]	65100075100330	6 tablets	1 tablet	NA
30 mg tablet[a]	65100075100340	6 tablets	1 tablet	NA
30 mg tablet	6510007510A560	6 tablets	1 tablet	NA
5 mg/5 mL solution[a]	65100075102005	180 mL	33 mL	NA
20 mg/mL concentrate[a]	65100075101320	9 mL	1 mL	NA
Opana (oxymorphone)[a]				
5 mg tablet	65100080100305	6 tablets	3 tablets	NA
10 mg tablet	65100080100310	6 tablets	1 tablet	NA
Nucynta (tapentadol)				
50 mg tablet	65100091100320	6 tablets	2 tablets	NA
75 mg tablet	65100091100330	6 tablets	1 tablet	NA
100 mg tablet	65100091100340	6 tablets	1 tablet	NA
Qdolo, Ultram, Tramadol				
25 mg tablet	65100095100310	8 tablets	10 tablets	≥18 years
50 mg tablet[a]	65100095100320	8 tablets	5 tablets	≥18 years
100 mg tablet[a]	65100095100340	4 tablets	3 tablets	≥18 years
5 mg/mL solution	65100095102005	80 mL	50 mL	≥18 years
COMBINATION INGREDIENT AGENT(S)				
Apadaz, Benzhydrocodone/acetaminophen				
4.08/325 mg tablet	65990002020310	12 tablets	11 tablets[‡]	NA
6.12/325 mg tablet	65990002020320	12 tablets	7 tablets[‡]	NA
8.16/325 mg tablet	65990002020330	12 tablets	6 tablets[‡]	NA
Tylenol w/Codeine (acetaminophen/codeine)[a]				
120 mg/12 mg/5 mL solution	65991002052020	90 mL	138 mL[‡]	≥18 years
300 mg/15 mg tablet	65991002050310	12 tablets	22 tablets[‡]	≥18 years
300 mg/30 mg tablet	65991002050315	12 tablets	11 tablets[‡]	≥18 years
300 mg/60 mg tablet	65991002050320	6 tablets	5 tablets[‡]	≥18 years

Fioricet w/Codeine (butalbital/acetaminophen/caffeine/codeine)[a]				
50 mg/300 mg/40 mg/30 mg capsule	65991004100113	6 capsules	11 capsules[‡]	≥18 years
50 mg/325 mg/40 mg/30 mg capsule	65991004100115	6 capsules	11 capsules[‡]	≥18 years
Fiorinal w/Codeine (butalbital/aspirin/caffeine/codeine)[a]				
50 mg/325 mg/40 mg/30 mg capsule	65991004300115	6 capsules	11 capsules[‡]	≥18 years
Trezix, Acetaminophen/caffeine/dihydrocodeine				
320.5 mg/30 mg/16 mg capsule	65991303050115	10 capsules	12 capsules[‡]	≥18 years
325 mg/30 mg/16 mg tablet	65991303050320	10 tablets	12 tablets[‡]	≥18 years
Lortab, Norco, Hydrocodone/acetaminophen				
5 mg/300 mg tablet[a]	65991702100309	8 tablets	10 tablets[‡]	NA
5 mg/325 mg tablet[a]	65991702100356	8 tablets	10 tablets[‡]	NA
7.5 mg/300 mg tablet[a]	65991702100322	6 tablets	6 tablets[‡]	NA
7.5 mg/325 mg tablet[a]	65991702100358	6 tablets	6 tablets[‡]	NA
10 mg/300 mg tablet[a]	65991702100375	6 tablets	5 tablets[‡]	NA
10 mg/325 mg tablet[a]	65991702100305	6 tablets	5 tablets[‡]	NA
7.5 mg/325 mg/15 mL solution[a]	65991702102015	90 mL	100 mL[‡]	NA
10 mg/300 mg/15 mL solution	65991702102024	67.5 mL	74 mL[‡]	NA
Hydrocodone/Ibuprofen				
5 mg/200 mg tablet	65991702500315	5 tablets	10 tablets[‡]	NA
7.5 mg/200 mg tablet[a]	65991702500320	5 tablets	6 tablets[‡]	NA
10 mg/200 mg tablet[a]	65991702500330	5 tablets	5 tablets[‡]	NA
Percocet, Prolate, Oxycodone/acetaminophen, Nalocet, Primlev				
2.5 mg/300 mg tablet	65990002200303	12 tablets	13 tablets[‡]	NA
2.5 mg/325 mg tablet[a]	65990002200305	12 tablets	13 tablets[‡]	NA
5 mg/300 mg tablet	65990002200308	12 tablets	6 tablets[‡]	NA
5 mg/325 mg tablet[a]	65990002200310	12 tablets	6 tablets[‡]	NA
7.5 mg/300 mg tablet	65990002200325	8 tablets	4 tablets[‡]	NA

7.5 mg/325 mg tablet[a]	65990002200327	8 tablets	4 tablets[‡]	NA
10 mg/300 mg tablet	65990002200333	6 tablets	3 tablets[‡]	NA
10 mg/325 mg tablet[a]	65990002200335	6 tablets	3 tablets[‡]	NA
10 mg/300 mg/5 mL solution	65990002202020	30 mL	15 mL[‡]	NA
5 mg/325 mg/5 mL solution	65990002202005	60 mL	30 mL[‡]	NA
Oxycodone/Ibuprofen				
5 mg/400 mg tablet	65990002260320	4 tablets	6 tablets[‡]	NA
pentazocine/naloxone[a]				
50 mg/0.5 mg tablet	65200040300310	12 tablets	2 tablets[‡]	NA
Seglentis (celecoxib/tramadol)				
56 mg/44 mg tablet	65995002100320	4 tablets	13 tablets[‡]	≥18 years
Ultracet (tramadol/acetaminophen)[a]				
37.5 mg/325 mg tablet	65995002200320	8 tablets	7 tablets	≥18 years

a - generic available
b - all target agents are subject to a ≤ 7 days of therapy and <50 morphine milligram equivalents per day if no prior opioid or oncology claims are found in the past 120 days
* - product minimum dosage strength surpasses 50 MME
‡ - quantity for being under 50 MME per day may exceed dosing limit of other ingredients in the combination product

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Target Agent(s) will be approved when ONE of the following is met:

1. The request exceeds the 7 day supply limit and/or the 50 morphine milligram equivalent per day limit AND ALL of the following:
    A. If the requested agent contains acetaminophen, then the requested dose of acetaminophen does NOT exceed 4 g/day
    AND
    B. If the requested agent contains tramadol, dihydrocodeine, OR codeine, then ONE of the following:
        i. The patient is 12 to less than 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy
        OR
        ii. The patient is 18 years of age or over
    AND
    C. ONE of the following:
        i. The requested quantity (dose) does NOT exceed the program daily quantity limit AND ONE of the following:
            a. There is information that the patient is NOT new to opioid therapy in the past 120 days
            OR
            b. The prescriber states the patient is NOT new to opioid therapy AND is at risk if therapy is changed
            OR

c. The patient has a claim for an oncology agent in the past 120 days
OR
d. BOTH of the following:
    1. ONE of the following:
        A. The patient has a diagnosis of chronic cancer pain due to an active malignancy
        OR
        B. The patient is eligible for hospice OR palliative care
        OR
        C. The patient has a diagnosis of sickle cell disease
        OR
        D. The patient is undergoing treatment of non-cancer pain and ALL of the following:
            i. The prescriber has provided information in support of use of immediate-release single or combination opioids for an extended duration (>7 days) and/or greater than a 50 morphine milligram equivalents (MME) per day
            AND
            ii. A formal, consultative evaluation which includes BOTH of the following was conducted:
                a. Diagnosis
                AND
                b. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy
            AND
            iii. A patient-specific pain management plan is on file for the patient
            AND
            iv. The prescriber has reviewed the patient's records in the state's prescribing drug monitoring program (PDMP) **AND** has determined that the opioid dosage and combinations within the patient's records do NOT indicate the patient is at high risk for overdose

    AND
    2. ONE of the following:
        A. The patient is not concurrently using buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment
        OR

B. The prescriber has provided information in support of use of opioids with buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment

OR

ii. The requested quantity (dose) exceeds the program daily quantity limit AND ALL of the following:
   a. ONE of the following:
      1. There is information that the patient is NOT new to opioid therapy in the past 120 days
         OR
      2. The prescriber states the patient is NOT new to opioid therapy AND is at risk if therapy is changed
         OR
      3. The patient has a claim for an oncology agent in the past 120 days
         OR
      4. The prescriber has provided information in support of use of immediate-release single or combination opioids for an extended duration (>7 days) and/or greater than a 50 morphine milligram equivalents (MME) per day

   AND

   b. ONE of the following:
      1. The patient has a diagnosis of chronic cancer pain due to an active malignancy
         OR
      2. The patient is eligible for hospice OR palliative care
         OR
      3. The patient has a diagnosis of sickle cell disease
         OR
      4. The patient is undergoing treatment of non-cancer pain and ALL of the following:
         A. A formal, consultative evaluation which includes BOTH of the following was conducted:
            i. Diagnosis
               AND
            ii. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy

         AND

         B. A patient-specific pain management plan is on file for the patient
            AND
         C. The prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP) **AND** has determined that the opioid dosages and combinations within the patient's records do

NOT indicate the patient is at high risk for overdose

AND

c. ONE of the following:
    1. The patient is not concurrently using buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment
    OR
    2. The prescriber has provided information in support of use of opioids with buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment

AND

d. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

AND

e. The prescriber has provided information in support of therapy with a higher dose for the requested indication

OR

2. The request does NOT exceed the 7 day supply limit nor the 50 morphine milligram equivalent per day limit; but the requested dose exceeds the program quantity daily limit AND ALL of the following:
    A. ONE of the following:
        i. The patient has a diagnosis of chronic cancer pain due to an active malignancy
        OR
        ii. The patient is eligible for hospice OR palliative care
        OR
        iii. The patient has a diagnosis of sickle cell disease
        OR
        iv. The patient is undergoing treatment of non-cancer pain and ALL of the following:
            a. A formal, consultative evaluation which includes BOTH of the following was conducted:
                1. Diagnosis
                AND
                2. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy

            AND

            b. A patient-specific pain management plan is on file for the patient

            AND

            c. The prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP) **AND** has determined that the opioid dosages and combinations within the patient's records do NOT indicate the patient is at high risk for overdose

    AND

    B. ONE of the following:

i. The patient is not concurrently using buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment
OR
ii. The prescriber has provided information in support of use of opioids with buprenorphine or buprenorphine/naloxone agent for opioid dependence treatment

AND

C. If the requested agent contains acetaminophen, then the requested dose of acetaminophen does NOT exceed 4 g/day

AND

D. If the requested agent contains tramadol, dihydrocodeine, OR codeine, then ONE of the following:
i. The patient is 12 to less than 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy
OR
ii. The patient is 18 years of age or over

AND

E. BOTH of the following:
i. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
AND
ii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

OR

3. The request does NOT exceed the 7 day supply limit nor the 50 morphine milligram equivalent per day limit nor the program quantity daily limit AND the requested agent contains tramadol, dihydrocodeine, OR codeine, then ONE of the following:
A. The patient is 12 to less than 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy
OR
B. The patient is 18 years of age or over

Length of Approval: 6 months