DURATION LIMIT CRITERIA

DRUG CLASS	**ACETAMINOPHEN/ASPIRIN/IBUPROFEN CONTAINING OPIOID ANALGESICS (BRAND AND GENERIC)***
(generic name)	**(acetaminophen and benzhydrocodone)** **(acetaminophen and codeine)** **(acetaminophen and hydrocodone)** **(acetaminophen and oxycodone)** **(acetaminophen and tramadol)** **(acetaminophen, caffeine, and dihydrocodeine)** **(aspirin and oxycodone)** **(celecoxib and tramadol)** **(ibuprofen and hydrocodone)**
Status: CVS Caremark Criteria	
Type: Duration Limit; Post Limit Criteria*	***Ref # 1358-E***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*
***1358-E may be used as a stand-alone criteria OR in combination with Opioids IR Combo Products Limit 1365-H. The Opioids IR Combo Products Limit 1365-H will be coded separately.*

FDA-APPROVED INDICATIONS

Apadaz (benzhydrocodone/acetaminophen)

Apadaz (benzhydrocodone and acetaminophen) is indicated for the 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.

Limitations of Use

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve Apadaz for use in patients for whom alternative treatment options [e.g., non-opioid analgesics]:

- Have not been tolerated, or are not expected to be tolerated,
- Have not provided adequate analgesia, or are not expected to provide adequate analgesia.

Codeine/Acetaminophen

Acetaminophen and codeine phosphate oral solution and tablets are indicated for the management of mild to moderate pain, where treatment with an opioid is appropriate and for which alternative treatments are inadequate.

Limitations of Use

Because of the risks of addiction, abuse, and misuse, with opioids, even at recommended doses, reserve acetaminophen and codeine phosphate oral solution and tablets for use in patients for whom alternative treatment options [e.g., non-opioid analgesics]:

- Have not provided adequate analgesia, or are not expected to provide adequate analgesia,
- Have not been tolerated, or are not expected to be tolerated.

Hydrocodone/Acetaminophen

Hydrocodone bitartrate and acetaminophen Tablets are indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Limitations of Use

Because of the risks of addiction, abuse, and misuse, with opioids, even at recommended doses, reserve hydrocodone bitartrate and acetaminophen Tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics):

- Have not been tolerated, or are not expected to be tolerated,
- Have not provided adequate analgesia, or are not expected to provide adequate analgesia.

Hydrocodone/Ibuprofen

Hydrocodone bitartrate and ibuprofen tablets are indicated for the short-term management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Limitations of Use

Carefully consider the potential benefits and risks of hydrocodone bitartrate and ibuprofen tablets and other treatment options before deciding to use hydrocodone bitartrate and ibuprofen tablets. Use the lowest effective dosage for the shortest duration consistent with individual treatment goals. Do not use hydrocodone bitartrate and ibuprofen tablets for the treatment of conditions such as osteoarthritis or rheumatoid arthritis.

Because of the risks of addiction, abuse, and misuse, with opioids, even at recommended doses, reserve hydrocodone bitartrate and ibuprofen tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics):

- Have not been tolerated, or are not expected to be tolerated,
- Have not provided adequate analgesia, or are not expected to provide adequate analgesia.

Lortab Elixir (hydrocodone/acetaminophen), Hydrocodone/Acetaminophen Solution

Hydrocodone bitartrate and acetaminophen oral solution is indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Limitations of Use

Because of the risks of addiction, abuse, and misuse, with opioids, even at recommended doses, reserve hydrocodone bitartrate and acetaminophen oral solution for use in patients for whom alternative treatment options (e.g., non-opioid analgesics):

- Have not been tolerated, or are not expected to be tolerated
- Have not provided adequate analgesia, or are not expected to provide adequate analgesia.

Nalocet, Percocet, Prolate Tablets (oxycodone/acetaminophen), Oxycodone/Acetaminophen Tablets

Oxycodone and acetaminophen tablets are indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Limitations of Use

Because of the risks of addiction, abuse, and misuse, with opioids, even at recommended doses, reserve oxycodone and acetaminophen for use in patients for whom alternative treatment options [e.g., non-opioid analgesics]:

- Have not been tolerated, or are not expected to be tolerated,
- Have not provided adequate analgesia, or are not expected to provide adequate analgesia.

Oxycodone/Aspirin

Oxycodone and aspirin tablets are indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Limitations of Use

Because of the risks of addiction, abuse, and misuse, with opioids, even at recommended doses, reserve oxycodone and aspirin tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics):

- Have not been tolerated, or are not expected to be tolerated,
- Have not provided adequate analgesia, or are not expected to provide adequate analgesia

Prolate Solution (oxycodone/acetaminophen), Oxycodone/Acetaminophen Solution

Oxycodone hydrochloride and acetaminophen oral solution is indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Limitations of Use

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve oxycodone hydrochloride and acetaminophen oral solution for use in patients for whom alternative treatment options [e.g., non-opioid analgesics]:

- Have not been tolerated, or are not expected to be tolerated,
- Have not provided adequate analgesia, or are not expected to provide adequate analgesia

Seglentis (tramadol/celecoxib)

Seglentis (tramadol and celecoxib) is indicated for the management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Limitations of Use

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve Seglentis (tramadol and celecoxib) for use in patients for whom alternative treatment options [e.g., non-opioid analgesics]:

- Have not been tolerated, or are not expected to be tolerated
- Have not provided adequate analgesia, or are not expected to provide adequate analgesia.

Trezix Capsules (acetaminophen/caffeine/dihydrocodeine), Acetaminophen/Caffeine/Dihydrocodeine Tablets

Acetaminophen, caffeine, dihydrocodeine bitartrate capsules and tablets are indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Limitations of Use

Because of the risks of addiction, abuse, and misuse, with opioids, even at recommended doses, reserve acetaminophen, caffeine, dihydrocodeine bitartrate capsules and tablets for use in patients for whom alternative treatment options [e.g., non-opioid analgesics]:

- Have not been tolerated, or are not expected to be tolerated
- Have not provided adequate analgesia, or are not expected to provide adequate analgesia

Ultracet (tramadol/acetaminophen)

Ultracet (tramadol and acetaminophen) tablets are indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Limitations of Use

Ultracet (tramadol and acetaminophen) tablets are indicated for short-term use of five days or less.

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve Ultracet (tramadol and acetaminophen) for use in patients for whom alternative treatment options [e.g., non-opioid analgesics]:

- Have not been tolerated, or are not expected to be tolerated,
- Have not provided adequate analgesia, or are not expected to provide adequate analgesia.

SCREENOUT LOGIC

If the patient has filled a prescription for at least a 1-day supply of a drug indicating the patient is being treated for cancer or sickle cell disease within the past 365 days under a prescription benefit administered by CVS Caremark, then 1) when using this program in combination with Opioids IR Combo Products Limit 1365-H, the claim will proceed to the subsequent initial quantity limit criteria (1365-H) OR 2) when using this as a stand-alone program, the requested drug will be paid under that prescription benefit.

If a claim is submitted with an ICD 10 diagnosis code indicating cancer, sickle cell disease, or palliative care under a prescription benefit administered by CVS Caremark, then 1) when using this program in combination with Opioids IR Combo Products Limit 1365-H, the claim will proceed to the subsequent initial quantity limit criteria (1365-H) OR 2) when using this as a stand-alone program, the requested drug will be paid under that prescription benefit.

If the patient has an ICD 10 diagnosis code indicating cancer or palliative care in their member health profile in the past 365 days, then 1) when using this program in combination with Opioids IR Combo Products Limit 1365-H, the claim will proceed to the subsequent initial quantity limit criteria (1365-H) OR 2) when using this as a stand-alone program, the requested drug will be paid under that prescription benefit.

If the patient has any history of an ICD 10 diagnosis code indicating sickle cell disease in their member health profile, then 1) when using this program in combination with Opioids IR Combo Products Limit 1365-H, the claim will proceed to the subsequent initial quantity limit criteria (1365-H) OR 2) when using this as a stand-alone program, the requested drug will be paid under that prescription benefit.

If a claim is submitted using a hospice patient residence code under a prescription benefit administered by CVS Caremark, then 1) when using this program in combination with Opioids IR Combo Products Limit 1365-H, the claim will proceed to the subsequent initial quantity limit criteria (1365-H) OR 2) when using this as a stand-alone program, the requested drug will be paid under that prescription benefit.

For patients with no prescription claims of a cancer drug or a sickle cell disease drug in the past 365 days, no ICD 10 diagnosis code indicating cancer, sickle cell disease, or palliative care submitted with their prescription claim, no ICD 10 diagnosis code indicating cancer or palliative care in their member health profile in the past 365 days, no history of an ICD 10 diagnosis code indicating sickle cell disease in their member health profile, or no hospice patient residence code submitted with their prescription claim:
If the patient has filled a prescription for at least an 8-day supply of an immediate-release (IR) or extended-release (ER) opioid agent indicated for the management of pain within prescription claim history in the past 90 days under a prescription benefit administered by CVS Caremark, then 1) when using this program in combination with Opioids IR Combo Products Limit 1365-H, the claim will proceed to the subsequent initial quantity limit criteria (1365-H) OR 2) when using this as a stand-alone program, the requested drug will be paid under that prescription benefit.

If the patient does not have at least an 8-day supply of an IR or ER opioid agent indicated for the management of pain within prescription claim history in the past 90 days (i.e., this is the patient's first fill of an opioid), and the incoming prescription drug is being filled for more than a 7-day supply, then the claim will reject with a message indicating that the patient can receive a 7-day supply (until 7-days of therapy in a 90-day period have been filled) or submit a prior authorization (PA). The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit. If using this program in combination with Opioids IR Combo Products Limit 1365-H, then subsequent initial quantity limits would apply. If the incoming prescription drug is being filled for less than a 7-day supply, then 1) when using this program in combination with Opioids IR Combo Products Limit 1365-H, the claim will proceed to the subsequent initial quantity limit criteria (1365-H) OR 2) when using this as a stand-alone program, the requested drug will be paid under that prescription benefit.

LIMIT CRITERIA (DAY SUPPLY)**
Acute pain duration limits do not apply if the patient has a drug in claims history in the past year that indicates the patient is being treated for cancer or sickle cell disease. In addition, acute pain duration limits will not apply if a prescription claim is submitted with an ICD 10 diagnosis code indicating cancer, sickle cell disease, or palliative care, if the patient has an ICD 10 diagnosis code indicating cancer or palliative care in their member health profile in the past 365 days, if the patient has a history of an ICD 10 diagnosis code indicating sickle cell disease in their member health profile, or if a prescription claim is submitted using a hospice patient residence code. When using this program in combination with Opioids IR Combo Products Limit 1365-H, the claim will proceed to the subsequent initial quantity limit

criteria (1365-H) OR when using this as a stand-alone program, the requested drug will be paid under that prescription benefit.

If the patient has filled a prescription for at least an 8-day supply of an immediate-release (IR) or extended-release (ER) opioid agent indicated for the management of pain within prescription claim history in the past 90 days under a prescription benefit administered by CVS Caremark, then 1) when using this program in combination with Opioids IR Combo Products Limit 1365-H, the claim will proceed to the subsequent initial quantity limit criteria (1365-H) OR 2) when using this as a stand-alone program, the requested drug will be paid under that prescription benefit.

If the patient does not have at least an 8-day supply of an IR or ER opioid agent indicated for the management of pain within prescription claim history in the past 90 days (i.e., this is the patient's first fill of an opioid), and the incoming prescription drug is being filled for more than a 7-day supply, then the claim will reject with a message indicating that the patient can receive a 7-day supply (until 7-days of therapy in a 90-day period have been filled) or submit a prior authorization (PA) for additional days supply. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit. If using this program in combination with Opioids IR Combo Products Limit 1365-H, then subsequent initial quantity limits would apply. If the incoming prescription drug is being filled for less than a 7-day supply, then 1) when using this program in combination with Opioids IR Combo Products Limit 1365-H, the claim will proceed to the subsequent initial quantity limit criteria (1365-H) OR 2) when using this as a stand-alone program, the requested drug will be paid under that prescription benefit.

For hydrocodone/ibuprofen tablets and tramadol/acetaminophen tablets:
A quantity of 50 tablets/month of hydrocodone/ibuprofen tablets or 40 tablets/month of tramadol/acetaminophen tablets is provided upon approval of the PA to allow coverage consistent with product labeling.

***1358-E may be used as a stand-alone criteria OR in combination with Opioids IR Combo Products Limit 1365-H. The Opioids IR Combo Products Limit 1365-H will be coded separately.*

COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:

For benzhydrocodone/acetaminophen, codeine/acetaminophen, dihydrocodeine/caffeine/acetaminophen, hydrocodone/acetaminophen, oxycodone/acetaminophen, oxycodone/aspirin, tramadol/celecoxib:

- The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through hospice or palliative care

OR

- The patient can safely take the requested dose based on their history of opioid use.
  [Note: The lowest effective dosage should be prescribed for opioid naïve patients.]
  AND
  - The patient has been evaluated and the patient will be monitored regularly for the development of opioid use disorder
    AND
    - The requested drug is being prescribed for moderate to severe CHRONIC pain where use of an opioid analgesic is appropriate.
      [Note: Chronic pain is generally defined as pain that typically lasts greater than 3 months.]
      AND
    - The patient's pain will be reassessed in the first month after the initial prescription or any dose increase AND every 3 months thereafter to ensure that clinically meaningful improvement in pain and function outweigh risks to patient safety

  OR
  - The patient requires extended treatment beyond 7 days for moderate to severe ACUTE pain where use of an opioid analgesic is appropriate

For hydrocodone/ibuprofen tablets and tramadol/acetaminophen tablets:

- The patient will not require use of MORE than the plan allowance of 50 tablets/month of hydrocodone/ibuprofen tablets OR 40 tablets/month of tramadol/acetaminophen tablets

Quantity Limits may apply.
Hydrocodone/Ibuprofen: 5 tablets/day AND 50 tablets/month
Tramadol/Acetaminophen: 8 tablets/day AND 40 tablets/month

RATIONALE

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. Acetaminophen/caffeine/dihydrocodeine, hydrocodone/acetaminophen, oxycodone/acetaminophen tablets, and oxycodone/aspirin are indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Codeine/acetaminophen is indicated for the management of mild to moderate pain, where treatment with an opioid is appropriate and for which alternative treatments are inadequate. Hydrocodone/ibuprofen containing opioid analgesics are indicated for the short-term management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Ultracet (tramadol/acetaminophen) and oxycodone/acetaminophen oral solution are indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Apadaz (benzhydrocodone/acetaminophen) is indicated for the 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. Seglentis (tramadol/celecoxib) is indicated for the management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve immediate-release combination product opioids for use in patients for whom alternative treatment options (e.g., non-opioid analgesics) 1) have not been tolerated or are not expected to be tolerated, or 2) have not provided adequate analgesia or are not expected to provide adequate analgesia.[1-23]

If the patient has filled a prescription for at least a 1-day supply of a drug indicating the patient is being treated for cancer or sickle cell disease (SCD) within the past 365 days under a prescription benefit administered by CVS Caremark, then 1) when using this program in combination with Opioids IR Combo Products Limit 1365-H, the claim will proceed to the subsequent initial quantity limit criteria (1365-H) OR 2) when using this as a stand-alone program, the requested drug will be paid under that prescription benefit.

If a claim is submitted with an ICD 10 diagnosis code indicating cancer, sickle cell disease, or palliative care under a prescription benefit administered by CVS Caremark, then 1) when using this program in combination with Opioids IR Combo Products Limit 1365-H, the claim will proceed to the subsequent initial quantity limit criteria (1365-H) OR 2) when using this as a stand-alone program, the requested drug will be paid under that prescription benefit.

If the patient has an ICD 10 diagnosis code indicating cancer or palliative care in their member health profile in the past 365 days, then 1) when using this program in combination with Opioids IR Combo Products Limit 1365-H, the claim will proceed to the subsequent initial quantity limit criteria (1365-H) OR 2) when using this as a stand-alone program, the requested drug will be paid under that prescription benefit.

If the patient has any history of an ICD 10 diagnosis code indicating sickle cell disease in their member health profile, then 1) when using this program in combination with Opioids IR Combo Products Limit 1365-H, the claim will proceed to the subsequent initial quantity limit criteria (1365-H) OR 2) when using this as a stand-alone program, the requested drug will be paid under that prescription benefit.

If a claim is submitted using a hospice patient residence code under a prescription benefit administered by CVS Caremark, then 1) when using this program in combination with Opioids IR Combo Products Limit 1365-H, the claim will proceed to the subsequent initial quantity limit criteria (1365-H) OR 2) when using this as a stand-alone program, the requested drug will be paid under that prescription benefit.

For patients with no prescription claims of a cancer drug or a sickle cell disease drug in the past 365 days, no ICD 10 diagnosis code indicating cancer, sickle cell disease, or palliative care submitted with their prescription claim, no ICD 10 diagnosis code indicating cancer or palliative care in their member health profile in the past 365 days, no history of an ICD 10 diagnosis code indicating sickle cell disease in their member health profile, or no hospice patient residence code submitted with their prescription claim:
If the patient has filled a prescription for at least an 8-day supply of an immediate-release (IR) or extended-release (ER) opioid agent indicated for the management of pain within prescription claim history in the past 90 days under a prescription benefit administered by CVS Caremark, then 1) when using this program in combination with Opioids IR Combo Products Limit 1365-H, the claim will proceed to the subsequent initial quantity limit criteria (1365-H) OR 2) when using this as a stand-alone program, the requested drug will be paid under that prescription benefit.

If the patient does not have at least an 8-day supply of an IR or ER opioid agent indicated for the management of pain within prescription claim history in the past 90 days (i.e., this is the patient's first fill of an opioid), and the incoming prescription drug is being filled for more than a 7-day supply, then the claim will reject with a message indicating that the patient can receive a 7-day supply (until 7-days of therapy in a 90-day period have been filled) or submit a prior authorization (PA). The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit. If using this program in combination with Opioids IR Combo Products Limit 1365-H, then subsequent initial quantity limits would apply. If the incoming prescription drug is being filled for less than a 7-day supply, then 1) when using this program in combination with Opioids IR Combo Products Limit 1365-H, the claim will proceed to the subsequent initial quantity limit criteria (1365-H) OR 2) when using this as a stand-alone program, the requested drug will be paid under that prescription benefit.

The Centers for Disease Control and Prevention (CDC) Clinical Practice Guideline for Prescribing Opioids for Pain provides recommendations for clinicians providing pain care, including those prescribing opioids for outpatients aged ≥ 18 years. The recommendations do not apply to pain related to sickle cell disease or cancer or to patients receiving palliative or end-of-life care.[24] The National Comprehensive Cancer Network (NCCN) guidelines for Adult Cancer Pain recommend for continuous pain, it is appropriate to give pain medication on a regular schedule with supplemental doses for breakthrough pain. Add an extended-release or long-acting formulation to provide background analgesia for control of chronic persistent pain controlled on stable doses of short-acting opioids. Allow rescue doses of short-acting opioids up to every 1 hour as needed.[26] The NCCN Palliative Care pain management recommendation is to treat according to NCCN guidelines for adult cancer pain management.[25] For patients with no prescription claims of a cancer drug in the past 365 days, no ICD 10 diagnosis code indicating cancer or palliative care submitted with their prescription claim, no ICD 10 diagnosis code indicating cancer or palliative care in their member health profile in the past 365 days, or no hospice patient residence code submitted with their prescription claim who are identified through the prior authorization criteria as having cancer, a terminal condition, or pain being managed through hospice or palliative care, acute pain duration limits will not apply (except if the request is for hydrocodone/ibuprofen tablets or tramadol/acetaminophen tablets due to maximum duration specified in product labeling). If using this program in combination with Opioids IR Combo Products Limit 1365-H, then subsequent initial quantity limits would apply to all patients regardless of concomitant conditions (e.g., active cancer treatment, palliative care, and end-of-life care) due to the non-opioid components.

According to the National Heart, Lung, and Blood Institute's (NHLBI) guidelines for Sickle Cell Disease (SCD), pain is the most common symptom of SCD. Pain can be acute, chronic, or an acute episode superimposed on chronic pain. Recurrent acute pain crises (also known as vaso-occlusive crises) are the most common manifestation of SCD. Chronic pain is also one of the most common chronic complications of SCD. Pain management must be guided by patient report of severity. No biomarkers or imaging studies can validate pain or assess its severity. Medications used to treat SCD-related pain should be tailored to the individual. For pain that is not relieved by nonsteroidal anti-inflammatory drugs (NSAIDs) or other measures, either short-acting or long-acting opioids may be used to manage pain in SCD.[27] For patients with no prescription claims of a sickle cell disease drug in the past 365 days, no ICD 10 diagnosis code indicating sickle cell disease submitted with their prescription claim, or no history of an ICD 10 diagnosis code indicating sickle cell disease in their member health profile who are identified through the prior authorization criteria as having sickle cell disease, acute pain duration limits will not apply (except if the request is for hydrocodone/ibuprofen tablets or tramadol/acetaminophen tablets due to maximum duration specified in product labeling). If using this program in

combination with Opioids IR Combo Products Limit 1365-H, then subsequent initial quantity limits would apply to all patients regardless of concomitant conditions (e.g., sickle cell disease) due to the non-opioid components.

Evidence exists from observational studies of an association between opioid use for acute pain and long-term opioid use. Opioids are sometimes needed for treatment of acute pain. When the diagnosis and severity of acute pain warrant use of opioids, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. For many common causes of nontraumatic, nonsurgical pain, when opioids are needed, a few days or less are often sufficient, and shorter courses can minimize the need to taper opioids to prevent withdrawal symptoms at the end of a course of opioids. Data suggest that pain improves within days for many patients with common types of acute pain in primary care or emergency department settings. Analysis of nationwide U.S. commercial insurance claims in 2014 found median durations of initial opioid analgesic prescriptions for acute pain indications in primary care settings were 4–7 days, suggesting that in most cases, clinicians considered an initial opioid prescription of 4-7 days duration sufficient.[24] Coverage is provided for up to 7 days initially to provide an amount sufficient for the treatment of acute pain.

Risks of opioid use, including risk for overdose and overdose death, increase continuously with dosage, and there is no single dosage threshold below which risks are eliminated. When opioids are initiated for opioid-naïve patients with acute, subacute or chronic pain, clinicians should prescribe the lowest effective dosage. For patients not already taking opioids, the lowest effective dose can be determined using product labeling as a starting point with calibration as needed based on the severity of pain and other clinical factors such as renal or hepatic insufficiency. If opioids are continued for subacute or chronic pain, clinicians should use caution when prescribing opioids at any dosage and should generally avoid dosage increases when possible.[24]

Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risks for opioid-related harms and discuss risk with patients. Clinicians should reevaluate patients who are at higher risk for opioid use disorder or overdose (e.g., patients with depression or other mental conditions, a history of substance use disorder, a history of overdose, taking ≥ 50 MME/day, or taking other central nervous system depressants with opioids) more frequently than every 3 months. Clinicians should regularly screen all patients for these conditions, which can change during the course of treatment.[24]

Clinicians should evaluate benefits and risks with patients within 1 to 4 weeks of starting opioid therapy for subacute or chronic pain or of dose escalation. Clinicians should regularly reevaluate benefits and risks of continued opioid therapy with patients. Clinicians should regularly reassess all patients receiving long-term opioid therapy, with a suggested interval of every 3 months or more frequently for most patients. If benefits do not outweigh risks of continued opioid therapy, clinicians should optimize other therapies and work closely with patients to taper opioids to lower dosages or if warranted based on the individual circumstances of the patient, appropriately taper and discontinue opioids.[24]

The quantities of 40 tablets/month of tramadol/acetaminophen tablets or 50 tablets/month of hydrocodone/ibuprofen tablets are provided upon approval of the PA to allow coverage consistent with product labeling. For the short-term (generally less than 10 days) management of acute pain, the recommended dose of hydrocodone bitartrate/ibuprofen is one tablet every four to six hours, as necessary. Dosages should not exceed five tablets in a 24-hour period.[8] Since hydrocodone bitartrate/ibuprofen is only indicated for short-term use, the criteria allow for a quantity sufficient for a 10-day supply (50 tablets). For the short-term (five days or less) management of acute pain, the recommended dose of Ultracet (tramadol/acetaminophen) is 2 tablets every 4 to 6 hours as needed for pain relief, up to a maximum of 8 tablets per day.[20] Since Ultracet is only indicated for short-term use, the criteria allow for a quantity sufficient for a 5-day supply (40 tablets).

Acute pain is usually sudden in onset and time limited (defined in the CDC clinical practice guideline as having a duration of <1 month) and often is caused by injury, trauma, or medical treatments such as surgery.[24] Therefore, the duration of approval for patients meeting coverage criteria for acute pain will be one month.

Unresolved acute pain or subacute pain (defined in the CDC clinical practice guideline as pain that has been present for 1-3 months) can evolve into chronic pain. Chronic pain typically lasts >3 months and can be the result of an underlying medical disease or conditional, injury, medical treatment, inflammation, or unknown cause. Clinical evidence reviews

found insufficient evidence to determine long-term benefits of opioid therapy for chronic pain and found an increased risk for serious harms related to long-term opioid therapy that appears to be dose dependent. Compared with placebo, at short-term follow-up (1 to < 6 months) opioids were associated with small mean improvements in pain intensity. Some evidence indicates that improvement in pain is reduced with longer duration of opioid therapy. No placebo-controlled trial evaluated effectiveness of opioids at intermediate (6 to < 12 months) or long-term (≥ 12 months follow-up).[24] Therefore, the duration of approval for patients meeting coverage criteria for chronic pain will be 6 months.

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Reviewed:	Medical Affairs: (DNC) 05/2016, 05/2017, 08/2017, 01/2018, 03/2018, 06/2018, 02/2019; (TKP) 03/2019; (DNC) 05/2019, 07/2019; (CHART) 01/30/2020, 07/23/20, 01/14/2021, 01/28/2021, 11/04/2021, 02/03/2022, 02/16/2023 External Review: 06/2016, 04/2017, 06/2017, 10/2017, 04/2018, 08/2018, 04/2019 (FYI), 04/2019, 06/2019 (FYI), 08/2019 (FYI), 04/2020, 10/2020, 02/2021 (FYI), 04/2021, 12/2021 (FYI), 04/2022, 04/2023

CRITERIA FOR APPROVAL

1	Which opioid combination product (brand or generic) is being requested? Please check the drug being requested. [] benzhydrocodone/ACETAMINOPHEN (if checked, go to 2) [] codeine/ACETAMINOPHEN (if checked, go to 2) [] dihydrocodeine/caffeine/ACETAMINOPHEN (if checked, go to 2) [] hydrocodone/ACETAMINOPHEN or hydrocodone/ACETAMINOPHEN (Lortab Elixir) (if checked, go to 2) [] hydrocodone/IBUPROFEN (if checked, go to 8) [] oxycodone/ACETAMINOPHEN (if checked, go to 2) [] oxycodone/ASPIRIN (if checked, go to 2) [] tramadol/ACETAMINOPHEN (if checked, go to 8) [] tramadol/CELECOXIB (Seglentis) (if checked, go to 2)		
2	Is the requested drug being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through hospice or palliative care? [If yes, then no further questions.]	Yes	No
3	Can the patient safely take the requested dose based on their history of opioid use? [Note: The lowest effective dosage should be prescribed for opioid naive patients.] [If no, then no further questions.]	Yes	No
4	Has the patient been evaluated and will the patient be monitored regularly for the development of opioid use disorder? [If no, then no further questions.]	Yes	No
5	Is the requested drug being prescribed for moderate to severe CHRONIC pain where use of an opioid analgesic is appropriate? [Note: Chronic pain is generally defined as pain that typically lasts greater than 3 months.] [If no, then skip to question 7.]	Yes	No
6	Will the patient's pain be reassessed in the first month after the initial prescription or any dose increase AND every 3 months thereafter to ensure that clinically meaningful improvement in pain and function outweigh risks to patient safety?	Yes	No

[No further questions.]

7	Does the patient require extended treatment beyond 7 days for moderate to severe ACUTE pain where use of an opioid analgesic is appropriate? [No further questions.]	Yes	No
8	Does the patient require use of MORE than the plan allowance of 5 tablets per day OR 50 tablets per month (quantity sufficient for a 10-day supply) of hydrocodone/IBUPROFEN tablets OR MORE than the plan allowance of 8 tablets per day OR 40 tablets per month (quantity sufficient for a 5-day supply) of tramadol/ACETAMINOPHEN tablets? [RPh Note: If yes, then deny and enter a partial approval for 5 tablets per day and 50 tablets per month of hydrocodone/IBUPROFEN tablets OR 8 tablets per day and 40 tablets per month of tramadol/ACETAMINOPHEN tablets.]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	1=2; 2=2; 3=2; 4=2; 5=8; 6=2; 7=2; 8=8; 9=2	N/A	
2.	Approve, 12 months	Go to 3	
3.	Go to 4	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you can safely take the drug based on your history of opioid use. Your request has been denied based on the information we have. [Short Description: Patient cannot safely take requested dose.]
4.	Go to 5	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you will be monitored regularly. Your request has been denied based on the information we have. [Short Description: Patient not monitored regularly for opioid use disorder.]
5.	Go to 6	Go to 7	
6.	Approve, 6 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you meet all of these conditions: - Your pain will be checked the first month after your initial prescription or after a dose increase and every 3 months after that - The benefits outweigh the risks of taking the medication Your request has been denied based on the information we have. [Short Description: Patient's pain is not being reassessed.]
7.	Approve, 1 month	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have any of these conditions: - Pain due to cancer, sickle cell disease, or a terminal condition - Pain being managed through hospice or palliative care

			- Moderate to severe chronic pain that requires treatment with an opioid - Moderate to severe acute pain that requires treatment with an opioid for more than seven days Your request has been denied based on the information we have. [Short Description: No approvable diagnosis.]
8.	Deny RPh Note: For the denial verbiage, only include the requested drug. Remove all the other drugs from the verbiage.	Approve, 1 month - 5 tablets/day AND 50 tablets/month of hydrocodone/ibuprofen tablets or - 8 tablets/day AND 40 tablets/month of tramadol/acetaminophen tablets	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to: - 5 tablets/day AND 50 tablets/month of hydrocodone/ibuprofen tablets - 8 tablets/day AND 40 tablets/month of tramadol/acetaminophen tablets Your request has been partially approved. You have been approved for the maximum quantity that your plan covers for a duration of 1 month. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity.]