

## DURATION LIMIT CRITERIA

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

\* Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated.

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

### FDA-APPROVED INDICATIONS

#### **Acetaminophen/opioid analgesic or aspirin/opioid analgesic combination products**

Acetaminophen/opioid analgesic and aspirin/opioid analgesic combination products 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/opioid and aspirin/opioid combination products 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

Opioids IR - APAP-ASA-IBU Combo Products - Acute Pain Duration Limit 1358-E 01-2018.doc

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

### **Benzhydrocodone/acetaminophen (Apadaz)**

Apadaz 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

### **Hydrocodone bitartrate/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 dose 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

### **Oxycodone/ibuprofen**

Oxycodone HCl and ibuprofen tablets are indicated for the 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.

#### Limitations of Use

- Carefully consider the potential benefits and risks of Oxycodone Hydrochloride and Ibuprofen Tablets and other treatment options before deciding to use Oxycodone Hydrochloride and Ibuprofen Tablets. Use the lowest effective dose for the shortest duration consistent with individual treatment goals.
- Because of the risks of addiction, abuse, and misuse, with opioids, even at recommended doses, reserve Oxycodone Hydrochloride 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

### **Tramadol/acetaminophen**

Ultracet (tramadol/acetaminophen) 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

- Ultracet 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 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

## **COVERAGE CRITERIA**

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

For hydrocodone/ibuprofen tablets, oxycodone/ibuprofen tablets, tramadol/acetaminophen tablets:

- The patient will not require use of MORE than any of the following: A) 50 tablets/month of hydrocodone/ibuprofen tablets B) 28 tablets/month of oxycodone/ibuprofen tablets, C) 40 tablets/month of tramadol/acetaminophen tablets

For acetaminophen/codeine, acetaminophen/hydrocodone, acetaminophen/oxycodone, acetaminophen/caffeine/dihydrocodeine, aspirin/oxycodone, aspirin/caffeine/dihydrocodeine:

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

**OR**

- 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.]

**OR**

- The patient requires extended treatment beyond 7 days for ongoing management of ACUTE pain

Quantity Limits may apply.

## **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 and aspirin containing opioid analgesics are indicated for the management of pain severe enough to require an opioid analgesic 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. Oxycodone HCl and ibuprofen tablets are indicated for the 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.

Ultracet (tramadol/acetaminophen) is 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.<sup>1-22</sup>

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 within the past 365 days under a prescription benefit administered by CVS Caremark, then 1) when using this program in combination with Opioids IR APAP-ASA-IBU 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 in the past 365 days:

If the patient has filled a prescription for at least a cumulative 7-day supply of an opioid agent indicated for the management of pain (immediate- or extended-release) 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 APAP-ASA-IBU 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 a cumulative 7-day supply of an opioid agent indicated for the management of pain (immediate- or extended-release) 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 cumulative 7-day supply, then the claim will reject with a message indicating that the patient can receive a 7-day supply 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 APAP-ASA-IBU 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 APAP-ASA-IBU 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) Guideline for Prescribing Opioids for Chronic Pain provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care.<sup>23</sup> National Comprehensive Cancer Network (NCCN) guidelines for Adult Cancer Pain recommend for continuous pain 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. When possible, use the same opioid for short-acting and extended-release forms. Allow rescue doses of short-acting opioids every 1 hour as needed.<sup>25</sup> The NCCN Palliative Care pain management recommendation is to treat according to NCCN guidelines for adult cancer pain management.<sup>24</sup> For patients with no prescription claims of a cancer drug in the past 365 days 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, oxycodone/ibuprofen tablets, tramadol/acetaminophen tablets due to maximum duration specified in product labeling). If using this program in combination with Opioids IR APAP-ASA-IBU 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 Center for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain, 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.<sup>23</sup> Coverage is provided for up to 7 days initially to provide an amount sufficient for the treatment of acute pain.

The quantities of 28 tablets/month of oxycodone/ibuprofen tablets, 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 dosage of all strengths 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.<sup>10</sup> 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 management of acute moderate to severe pain, the recommended dose of oxycodone HCl and ibuprofen is one tablet every 6 hours as needed for pain. Dosage should not exceed 4 tablets in a 24-hour period and should not exceed 7 days.<sup>14</sup> Since oxycodone/ibuprofen is only indicated for short-term use, the criteria allow for a quantity sufficient for a 7-day supply (28 tablets).

For the short-term (five days or less) management of acute pain, the recommended dose of Ultracet is 2 tablets every 4 to 6 hours as needed for pain relief, up to a maximum of 8 tablets per day.<sup>18</sup> Since Ultracet is only indicated for short-term use, the criteria allow for a quantity sufficient for a 5-day supply (40 tablets).

## **PROGRAM DESCRIPTION\*\***

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.

### **Acute Pain Duration Limit**

If the patient has filled a prescription for at least a cumulative 7-day supply of an opioid agent indicated for the management of pain (immediate- or extended-release) 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 APAP-ASA-IBU 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 a cumulative 7-day supply of an opioid agent indicated for the management of pain (immediate- or extended-release) within prescription claim history in the past 90 days (i.e., this is the patient's first fill of an opioid) , then coverage is provided for up to a 7-day supply of the immediate-release opioid. Prior authorization review is required to determine coverage for a quantity necessary for treatment beyond 7 days. For patients with no prescription claims of a cancer drug in the past 365 days 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. If using this program in combination with Opioids IR APAP-ASA-IBU 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.

For hydrocodone/ibuprofen tablets, oxycodone/ibuprofen tablets, tramadol/acetaminophen tablets:

A quantity of 28 tablets/month of oxycodone/ibuprofen tablets, 40 tablets/month of tramadol/acetaminophen tablets, or 50 tablets/month of hydrocodone/ibuprofen 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 APAP-ASA-IBU Combo Products Limit 1365-H.*

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Written by: UM Development (CF/JH)  
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 External Review: 06/2016, 04/2017, 06/2017, 10/2017, 04/2018

### **INITIAL STEP THERAPY**

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 within the past 365 days under a prescription benefit administered by CVS Caremark, then 1) when using this program in combination with Opioids IR APAP-ASA-IBU 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 in the past 365 days:**

If the patient has filled a prescription for at least a cumulative 7-day supply of an opioid agent indicated for the management of pain (immediate- or extended-release) 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 APAP-ASA-IBU 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 a cumulative 7-day supply of an opioid agent indicated for the management of pain (immediate- or extended-release) 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 cumulative 7-day supply, then the claim will reject with a message indicating that the patient can receive a 7-day supply 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 APAP-ASA-IBU 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 APAP-ASA-IBU 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. When using this program in combination with Opioids IR APAP-ASA-IBU 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 a cumulative 7-day supply of an opioid agent indicated for the management of pain (immediate- or extended-release) 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 APAP-ASA-IBU 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 a cumulative 7-day supply of an opioid agent indicated for the management of pain (immediate- or extended-release) 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 cumulative 7-day supply, then the claim will reject with a message indicating that the patient can receive a 7-day supply 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 APAP-ASA-IBU 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 APAP-ASA-IBU 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, oxycodone/ibuprofen tablets, tramadol/acetaminophen tablets:  
A quantity of 28 tablets/month of oxycodone/ibuprofen tablets, 40 tablets/month of tramadol/acetaminophen tablets, or 50 tablets/month of hydrocodone/ibuprofen 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 APAP-ASA-IBU Combo Products Limit 1365-H. The Opioids IR APAP-ASA-IBU Combo Products Limit 1365-H will be coded separately.*

**CRITERIA FOR APPROVAL**

Is one of the following opioid combination products (brand or generic) being requested: A) hydrocodone/IBUPROFEN tablets, B) oxycodone/IBUPROFEN tablets, C) tramadol/ACETAMINOPHEN tablets? Yes No  
[If yes, then skip to question 5.]

Is the requested drug being prescribed for pain associated with cancer, a terminal condition, or pain being managed through hospice or palliative care? Yes No  
[If yes, then no further questions.]

Is the requested drug being prescribed for moderate to severe CHRONIC pain where use of an opioid analgesic is appropriate? Yes No  
[Note: Chronic pain is generally defined as pain that typically lasts greater than 3 months.]  
[If yes, then no further questions.]

Does the patient require extended treatment beyond 7 days for ongoing management of ACUTE pain? [No further questions.]	Yes	No
Does the patient require use of MORE than any of the following: A) 50 tablets/month of hydrocodone/IBUPROFEN tablets B) 28 tablets/month of oxycodone/IBUPROFEN tablets, C) 40 tablets/month of tramadol/ACETAMINOPHEN tablets?	Yes	No
[RPh Note: If yes, then deny and enter a partial approval for 50 tablets/month of hydrocodone/ibuprofen tablets B) 28 tablets/month of oxycodone/ibuprofen tablets, C) 40 tablets/month of tramadol/acetaminophen tablets.]		

Mapping Instructions		
Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D
Go to 5	Go to 2	
Approve, 12 months	Go to 3	
Approve, 12 months	Go to 4	
Approve, 1 month	Deny	<p>Your plan covers this drug when you have one of these conditions:</p> <ul style="list-style-type: none"> <li>- Pain due to cancer or a terminal condition</li> <li>- Pain being managed through hospice or palliative care</li> <li>- Moderate to severe chronic pain that requires opioids</li> <li>- Acute pain that requires opioids for more than 7 days</li> </ul> <p>Your use of this drug does not meet the requirement. This is based on the information we have.</p> <p>[Short Description: No approvable diagnosis.]</p>
Deny RPh Note: For the denial verbiage, only include the requested drug. Remove all the other drugs from the verbiage.	Approve, 1 month - 50 tablets/month of hydrocodone/ibuprofen tablets or - 28 tablets/month of oxycodone/ibuprofen tablets or - 40 tablets/month of tramadol/APAP tablets	<p>You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to:</p> <ul style="list-style-type: none"> <li>- 50 tablets/month of hydrocodone/ibuprofen tablets or</li> <li>- 28 tablets/month of oxycodone/ibuprofen tablets or</li> <li>- 40 tablets/month of tramadol/acetaminophen tablets</li> </ul> <p>You have been approved for the maximum quantity that your plan covers for 1 month. Your request for additional quantities of the requested drug and strength has been denied.</p> <p>[Short Description: Over max quantity.]</p>



