

DURATION LIMIT CRITERIA

DRUG CLASS ACETAMINOPHEN/ASPIRIN/IBUPROFEN CONTAINING OPIOID ANALGESICS (BRAND AND GENERIC)

(generic)*

(acetaminophen and benzhydrocodone)

(acetaminophen and codeine)

(acetaminophen and hydrocodone)

(acetaminophen and oxycodone)

(acetaminophen and tramadol)

(acetaminophen, caffeine, and dihydrocodeine)

(aspirin and oxycodone)

(aspirin, caffeine, and dihydrocodeine)

(ibuprofen and hydrocodone)

(ibuprofen and oxycodone)

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 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/Caffeine/Dihydrocodeine

Acetaminophen/caffeine/dihydrocodeine bitartrate 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 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.

Aspirin/Caffeine/Dihydrocodeine

For the relief of moderate to moderately severe pain.

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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.

Codeine/Acetaminophen

Oral Solution and Tablets

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, suspension, 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 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 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.

Oxycodone/Acetaminophen

Oxycodone and acetaminophen 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 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

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- 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.

Oxycodone/Ibuprofen

Oxycodone hydrochloride 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) 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/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/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.

COVERAGE CRITERIA

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

For acetaminophen/benzhydrocodone, 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, 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

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

- The patient will not require use of MORE than the plan allowance of 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

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/caffeine/dihydrocodeine, hydrocodone/acetaminophen, oxycodone/acetaminophen, and oxycodone/aspirin are indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Aspirin/caffeine/dihydrocodeine is indicated for the relief of moderate to moderately severe pain. 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. Oxycodone/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. 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.¹⁻²²

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 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 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 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 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 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 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 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 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 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.

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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 a 7-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 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 7-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 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 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, sickle cell disease, palliative care, and end-of-life care.²³ 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.²⁵ The NCCN Palliative Care pain management recommendation is to treat according to NCCN guidelines for adult cancer pain management.²⁴ 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, 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 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.²⁶ 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, oxycodone/ibuprofen tablets, tramadol/acetaminophen tablets due to maximum duration specified in product labeling). If

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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., sickle cell disease) 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 not prescribe a 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.²³ Coverage is provided for up to 7 days initially to provide an amount sufficient for the treatment of acute pain.

Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, then clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.²³

Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should consider history of overdose, history of substance use disorder, higher opioid dosages [≥ 50 morphine milligram equivalents per day (MME/day)], or concurrent benzodiazepine use.²³

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 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.⁹ 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 to moderate pain severe enough to require an opioid analgesic, the recommended dose of oxycodone/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.¹⁴ 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 (tramadol/acetaminophen) is 2 tablets every 4 to 6 hours as needed for pain relief, up to a maximum of 8 tablets per day.¹⁸ Since Ultracet is only indicated for short-term use, the criteria allow for a quantity sufficient for a 5-day supply (40 tablets).

Studies of opioid therapy for chronic pain that did not have a nonopioid control group have found that although many patients discontinue opioid therapy for chronic noncancer pain due to adverse effects or insufficient pain relief, there is weak evidence that patients who are able to continue opioid therapy for at least six months can experience clinically significant pain relief and insufficient evidence that function or quality of life improves. These findings suggest that it is very difficult for clinicians to predict whether benefits of opioids for chronic pain will outweigh risks of ongoing treatment for individual patients.²³ Therefore, patients who meet the prior authorization criteria for chronic pain will be approved for 6 months.

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Written by: UM Development (CF/JH)
 Date Written: 04/2016
 Revised: 01/2017 (no clinical changes), 03/2017 (clarified step language; no clinical changes), 05/2017 (added APAP/Caff/Dihydrocodeine 325-30-16 mg), 08/2017 (7-day supply, specified qtys for hydrocodone/IBU, oxycodone/IBU, tramadol/APAP), 01/2018, 03/2018 (added Apadaz), 06/2018 (added Nalocet); (CF/DS) 01/2019 (added two new strengths of Apadaz, added SCD), 05/2019 (added ICD10 code and hospice screenouts), 07/2019 (added member health profile screenout), 01/2020 (member health profile lifetime for SCD); (DS) 07/2020 (decreased DOA for chronic pain to 6 months), 01/2021 (added oxy/APAP solution 10/300)
 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
 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)

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 APAP-ASA-IBU Combo Products Limit 1365-H, the claim will proceed

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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 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 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 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 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 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 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 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 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 a 7-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 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 7-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 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 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 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

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profile, or if a prescription claim is submitted using a hospice patient residence code. 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 7-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 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 7-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 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

1 Which opioid combination product (brand or generic) is being requested? Please check the drug being requested.

- benzhydrocodone/ACETAMINOPHEN (Apadaz) (if checked, go to 2)
- codeine/ACETAMINOPHEN (if checked, go to 2)
- dihydrocodeine/caffeine/ACETAMINOPHEN (if checked, go to 2)
- dihydrocodeine/caffeine/ASPIRIN (if checked, go to 2)
- hydrocodone/ACETAMINOPHEN (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)
- oxycodone/IBUPROFEN (if checked, go to 8)
- tramadol/ACETAMINOPHEN (if checked, go to 8)

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? Yes No
[If yes, then no further questions.]

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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 naïve patients.]	Yes	No
4	Has the patient been evaluated and will the patient be monitored regularly for the development of opioid use disorder?	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? [No further questions.]	Yes	No
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 any of the following: A) 50 tablets/month of hydrocodone/IBUPROFEN tablets, B) 40 tablets/month of tramadol/ACETAMINOPHEN tablets, C) 28 tablets/month of oxycodone/IBUPROFEN tablets? [RPh Note: If yes, then deny and enter a partial approval for ONE of the following: A) 50 tablets/month of hydrocodone/IBUPROFEN tablets, B) 40 tablets/month of tramadol/ACETAMINOPHEN tablets, C) 28 tablets/month of oxycodone/IBUPROFEN 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=2; 6=8; 7=2; 8=2; 9=8; 10=8	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

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			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 one 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 - 50 tablets/month of hydrocodone/ibuprofen tablets or - 40 tablets/month of tramadol/APAP tablets or - 28 tablets/month of oxycodone/ibuprofen tablets	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to: - 50 tablets/month of hydrocodone/ibuprofen tablets - 40 tablets/month of tramadol/acetaminophen tablets - 28 tablets/month of oxycodone/ibuprofen tablets 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.]