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: Initial Step; Duration Limit; Post Limit Criteria

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

POLICY

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.

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.
Oral Suspension
Acetaminophen and codeine phosphate oral suspension is indicated for the management of mild to moderate 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 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

- 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.

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 or sickle cell disease.

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, the claim will proceed to the subsequent initial quantity limit criteria 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 combination product 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 or a sickle cell disease drug in the past 365 days who are identified through the prior authorization criteria as having cancer, sickle cell disease, 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, then subsequent initial quantity limits would apply to all patients regardless of concomitant conditions (e.g., active cancer treatment, sickle cell disease, 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.

***The criteria may be used as a stand-alone criteria OR in combination with Opioids IR APAP-ASA-IBU Combo Products Limit.*

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 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, the claim will proceed to the subsequent initial quantity limit criteria 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:
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, the claim will proceed to the subsequent initial quantity limit criteria 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). 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, 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, the claim will proceed to the subsequent initial quantity limit criteria 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. When using this program in combination with Opioids IR APAP-ASA-IBU Combo Products Limit, the claim will proceed to the subsequent initial quantity limit criteria 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, the claim will proceed to the subsequent initial quantity limit criteria 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, 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, the claim will proceed to

the subsequent initial quantity limit criteria 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.

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

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 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

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 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.

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