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)
	(celecoxib and tramadol)
	(ibuprofen and hydrocodone)
	(ibuprofen and oxycodone)
Status: CVS Caremark Criteria	
Type: Duration Limit; Post Limit Criteria	

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

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

- 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.

Tramadol/Celecoxib
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.
Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve Seglentis (tramadol/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.

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, 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.

***These criteria may be used as a stand-alone criteria OR in combination with Opioids IR Combo Products Limit. The Opioids IR 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 acetaminophen/benzhydrocodone, acetaminophen/codeine, acetaminophen/hydrocodone, acetaminophen/oxycodone, acetaminophen/caffeine/dihydrocodeine, aspirin/oxycodone, celecoxib/tramadol:

- 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, 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.

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