DURATION LIMIT CRITERIA

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

Prior authorization applies only to patients ≤ 19 years of age.

(generic name)

(acetaminophen and benzhydrocodone)

(acetaminophen and codeine)

(acetaminophen and hydrocodone)

(acetaminophen and oxycodone)

(acetaminophen and tramadol)

(acetaminophen, caffeine, and dihydrocodeine)

(aspirin and oxycodone)

(celecoxib and tramadol)

(ibuprofen and hydrocodone)

Status: CVS Caremark® Criteria
Type: Duration Limit; Post Limit Criteria

POLICY

FDA-APPROVED INDICATIONS

Apadaz (benzhydrocodone/acetaminophen)

Apadaz (benzhydrocodone and acetaminophen) is indicated for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Limitations of Use

Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, reserve Apadaz (benzhydrocodone 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.

Apadaz (benzhydrocodone and acetaminophen) should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.

Codeine/Acetaminophen
Acetaminophen and codeine phosphate oral solution and tablets are indicated for the management of mild to moderate pain, where treatment with an opioid is appropriate and for which alternative treatments are inadequate.
Limitations of Use
Because of the risks of addiction, abuse, and misuse, with opioids, which can occur at any dosage or duration, reserve acetaminophen and codeine phosphate oral solution and tablets for use in patients for whom alternative treatment options [e.g., non-opioid analgesics]:

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

Acetaminophen and codeine phosphate tablets should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.

Hydrocodone/Acetaminophen
Hydrocodone bitartrate and acetaminophen tablets are indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.
Limitations of Use
Because of the risks of addiction, abuse, and misuse, with opioids, which can occur at any dosage or duration, reserve hydrocodone bitartrate and acetaminophen tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics):

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

Hydrocodone bitartrate and acetaminophen tablets should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.

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, which can occur at any dosage or duration, 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.

Hydrocodone bitartrate and ibuprofen tablets should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.

Lortab Elixir (hydrocodone/acetaminophen), Hydrocodone/Acetaminophen Solution
Hydrocodone bitartrate and acetaminophen oral solution is indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.
Limitations of Use

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

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

Nalocet, Percocet, Prolate Tablets (oxycodone/acetaminophen), Oxycodone/Acetaminophen Tablets
Oxycodone and acetaminophen tablets are indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.
Limitations of Use
Because of the risks of addiction, abuse, and misuse, with opioids, which can occur at any dosage or duration, reserve oxycodone and acetaminophen tablets for use in patients for whom alternative treatment options [e.g., non-opioid analgesics]:

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

Oxycodone and acetaminophen tablets should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.

Oxycodone/Aspirin
Oxycodone and aspirin tablets are indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.
Limitations of Use
Because of the risks of addiction, abuse, and misuse, with opioids, even at recommended doses, reserve oxycodone and aspirin tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics):

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

Prolate Solution (oxycodone/acetaminophen), Oxycodone/Acetaminophen Solution
Oxycodone hydrochloride and acetaminophen oral solution is indicated for the management of 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, which can occur at any dosage or duration, reserve oxycodone hydrochloride and acetaminophen oral solution for use in patients for whom alternative treatment options [e.g., non-opioid analgesics]:

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

Oxycodone hydrochloride and acetaminophen oral solution should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.

Seglentis (tramadol/celecoxib)
Seglentis (tramadol and celecoxib) is indicated for the management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate.
Limitations of Use
Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, reserve Seglentis (tramadol and celecoxib) for use in patients for whom alternative treatment options [e.g., non-opioid analgesics]:

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

Seglentis (tramadol and celecoxib) should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.

Trezix Capsules (acetaminophen/caffeine/dihydrocodeine), Acetaminophen/Caffeine/Dihydrocodeine Tablets
Acetaminophen, caffeine, dihydrocodeine bitartrate capsules and tablets are indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.
Limitations of Use
Because of the risks of addiction, abuse, and misuse, with opioids, even at recommended doses, reserve acetaminophen, caffeine, dihydrocodeine bitartrate capsules and tablets for use in patients for whom alternative treatment options [e.g., non-opioid analgesics]:

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

Ultracet (tramadol/acetaminophen)
Ultracet (tramadol and acetaminophen) tablets are indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.
Limitations of Use
Ultracet (tramadol and acetaminophen) tablets are indicated for short-term use of five days or less.
Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve Ultracet (tramadol and acetaminophen) for use in patients for whom alternative treatment options [e.g., non-opioid analgesics]:

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

SCREENOUT LOGIC
If the patient is ≤ 19 years of age and 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 the claim will proceed to the subsequent initial quantity limit criteria Opioids IR Combo Products Limit 1365-H.

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 the claim will proceed to the subsequent initial quantity limit criteria Opioids IR Combo Products Limit 1365-H.

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 the claim will proceed to the subsequent initial quantity limit criteria Opioids IR Combo Products Limit 1365-H.

If the patient has any history of an ICD 10 diagnosis code indicating sickle cell disease in their member health profile, then the claim will proceed to the subsequent initial quantity limit criteria Opioids IR Combo Products Limit 1365-H.

If a claim is submitted using a hospice patient residence code under a prescription benefit administered by CVS Caremark, then the claim will proceed to the subsequent initial quantity limit criteria Opioids IR Combo Products Limit 1365-H.

For patients ≤ 19 years of age 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 is ≤ 19 years of age and 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 the claim will proceed to the subsequent initial quantity limit criteria Opioids IR Combo Products Limit 1365-H.

If the patient is ≤ 19 years of age and 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, and the incoming prescription drug is being filled for more than a 3-day supply, then the claim will reject with a message indicating that the patient can receive a 3-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. The subsequent initial quantity limits from the Opioids IR Combo Products Limit 1365-H would then apply. If the incoming prescription drug is being filled for less than a 3-day supply, then the claim will proceed to the subsequent initial quantity limit criteria Opioids IR Combo Products Limit 1365-H.

LIMIT CRITERIA (DAY SUPPLY)**

Acute pain duration limits do not apply if the patient is ≤ 19 years of age and 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. The subsequent initial quantity limits from the Opioids IR Combo Products Limit 1365-H would then 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.

If the patient is ≤ 19 years of age and 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 the claim will proceed to the subsequent initial quantity limit criteria Opioids IR Combo Products Limit 1365-H.

If the patient is ≤ 19 years of age and 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, and the incoming prescription drug is being filled for more than a 3-day supply, then the claim will reject with a message indicating that the patient can receive a 3-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. The subsequent initial quantity limits from the Opioids IR Combo Products Limit 1365-H would then apply. If the incoming prescription drug is being filled for less than a 3-day supply, then the claim will proceed to the subsequent initial quantity limit criteria Opioids IR Combo Products Limit 1365-H.

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

***2888-E will be used in combination with Opioids IR Combo Products Limit 1365-H. The Opioids IR Combo Products Limit 1365-H will be coded separately. Opioids ER - Step Therapy with MME Limit and Post Limit 2219-M will be implemented for patients ≤ 19 years of age to ensure that these patients will not receive an extended-release opioid if opioid naïve. Any existing Utilization Management opioid programs will remain unchanged for patients 20 years of age or older.*

COVERAGE CRITERIA

[NOTE: These drugs should be prescribed only by health care professionals who are knowledgeable about the use of opioids and how to mitigate the associated risks.]

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

Pain associated with Cancer, Sickle Cell Disease, a Terminal Condition, or Pain being managed through Hospice or Palliative Care
Authorization may be granted when 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

Acute Pain
Authorization may be granted when the patient requires treatment for ACUTE pain severe enough to require an opioid analgesic when ALL of the following criteria are met:
[NOTE: Many acute pain conditions (e.g., the pain that occurs with a number of surgical procedures or acute musculoskeletal injuries) require no more than a few days of an opioid analgesic.]

- The patient can safely take the requested dose based on their history of opioid use [NOTE: The lowest dosage necessary to achieve adequate analgesia should be prescribed.]
- The patient has been evaluated and the patient will be monitored regularly for the development of opioid use disorder

Chronic Pain
Authorization may be granted when the requested drug is being prescribed for CHRONIC pain severe enough to require an opioid analgesic when ALL of the following criteria are met:
[NOTE: Chronic pain is generally defined as pain that typically lasts greater than 3 months.]

- The patient can safely take the requested dose based on their history of opioid use [NOTE: The lowest dosage necessary to achieve adequate analgesia should be prescribed.]
- The patient has been evaluated and the patient will be monitored regularly for the development of opioid use disorder
- 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 [NOTE: Because the risk of overdose increases as opioid doses increase, reserve titration to higher doses for patients in whom lower doses are insufficiently effective and in whom the expected benefits of using a higher dose opioid clearly outweigh the substantial risks.]

For hydrocodone/ibuprofen tablets and tramadol/acetaminophen tablets:

Authorization may be granted for the requested drug when the following criteria is met:

- The patient will NOT require use of MORE than the plan allowance of ANY of the following: 5 tablets per day OR 50 tablets per month (quantity sufficient for a 10-day supply) of hydrocodone/IBUPROFEN tablets, 8 tablets per day OR 40 tablets per month (quantity sufficient for a 5-day supply) of tramadol/ACETAMINOPHEN tablets

QUANTITY LIMITS MAY APPLY
Hydrocodone/ibuprofen: 5 tablets per day AND 50 tablets per month
Tramadol/Acetaminophen: 8 tablets per day AND 40 tablets per month

DURATION OF APPROVAL (DOA)

- 2888-E:
  - Benzhydrocodone/acetaminophen, codeine/acetaminophen, dihydrocodeine/caffeine/acetaminophen, hydrocodone/acetaminophen, oxycodone/acetaminophen, oxycodone/aspirin, tramadol/celecoxib:
    - Pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through hospice or palliative care: DOA: 12 months
    - Chronic pain: DOA: 6 months
    - Acute pain: DOA: 1 month
  - Hydrocodone/ibuprofen tablets and tramadol/acetaminophen tablets: DOA: 1 month

REFERENCES

1. Acetaminophen and Codeine Phosphate Solution [package insert]. Gurnee, IL: Akorn Operating Company LLC; August 2022.
2. Acetaminophen and Codeine Phosphate Tablet [package insert]. Webster Groves, MO: SpecGx LLC; November 2023.
3. Acetaminophen, Caffeine, and Dihydrocodeine Bitartrate Tablet [package insert]. Canton, MS: Larken Laboratories, Inc.; January 2021.
4. Apadaz [package insert]. Celebration, FL: Zevra Therapeutics, Inc.; December 2023.
5. Hydrocodone Bitartrate and Acetaminophen Solution [package insert]. Princeton, NJ: Eywa Pharma Inc.; October 2022.
6. Hydrocodone Bitartrate and Acetaminophen Tablets 5/300 mg, 7.5/300 mg, 10/300 mg, 5/325 mg, 7.5/325 mg, 10/325 mg [package insert]. Newtown, PA: KVK-Tech, Inc.; November 2023.
7. Hydrocodone Bitartrate and Ibuprofen Tablet [package insert]. Brookhaven, NY: Amneal Pharmaceuticals of NY, LLC; December 2023.
8. Lortab Elixir [package insert]. Atlanta, GA: Mikart, LLC; May 2021.
9. Nalocet [package insert]. Las Vegas, NV: Forte Bio-Pharma LLC; May 2021.
10. Oxycodone and Acetaminophen Tablet [package insert]. Newtown, PA: KVK-Tech, Inc.; December 2023.
11. Oxycodone and Acetaminophen Oral Solution 5 mg/325 mg [package insert]. Newtown, PA: KVK-Tec, Inc.; September 2023.
12. Oxycodone and Acetaminophen Oral Solution 10 mg/300 mg [package insert]. Las Vegas, NV: FH2 Pharma LLC; June 2023.
13. Oxycodone and Aspirin [package insert]. Laurelton, NY: Epic Pharma, LLC; July 2020.
14. Percocet [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; August 2020.
15. Prolate Solution [package insert]. Las Vegas, NV: Forte Bio-Pharma LLC; May 2021.
16. Prolate Tablet [package insert]. Las Vegas, NV: Forte Bio-Pharma LLC; June 2021.
17. Seglentis [package insert]. Montgomery, AL: Kowa Pharmaceuticals America, Inc; December 2023.
18. Trezix [package insert]. Ridgeland, MS: WraSer Pharmaceuticals; July 2017.
19. Ultracet [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; September 2021.
20. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed November 7, 2023.
21. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed November 7, 2023.
22. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 11/07/2023).
23. Dowell D, Ragan, KR, Jones, CM, et al; CDC Clinical Practice Guideline for Prescribing Opioids for Pain – United States, 2022. MMWR Recomm Rep. 2022;71:1–95. Available at: http://dx.doi.org/10.15585/mmwr.rr7103a1. Accessed November 7, 2023.
24. Palliative Care. NCCN Guidelines version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/palliative.pdf. Accessed November 7, 2023.
25. Adult Cancer Pain. NCCN Guidelines version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf. Accessed November 7, 2023.
26. National Heart, Lung, and Blood Institute. Evidence-Based Management of Sickle Cell Disease: Expert Panel Report, 2014. Available at: https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_0.pdf. Accessed November 7, 2023.
27. U.S. Food & Drug Administration. FDA updates prescribing information for all opioid pian medicines to provide additional guidance for safe use. April 13, 2023. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-prescribing-information-all-opioid-pain-medicines-provide-additional-guidance-safe-use. Accessed January 4, 2024.