

DURATION LIMIT CRITERIA

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

Prior authorization applies only to patients \leq 19 years of age.

(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**

This criteria will be used in combination with Opioids IR APAP-ASA-IBU Combo Products Limit. The Opioids IR APAP-ASA-IBU Combo Products Limit will be coded separately. Opioids ER - Step Therapy with MME Limit and Post Limit will be implemented for patients \leq 19 years of age to ensure that these patients will not receive an extended-release opioid if opioid naive. Any existing Utilization Management opioid programs will remain unchanged for patients 20 years of age or older.

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,

OPIOID-3.DOC

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

- 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.

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

OPIOID-3.DOC

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

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.

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 APAP-ASA-IBU 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 APAP-ASA-IBU 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 APAP-ASA-IBU 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 APAP-ASA-IBU 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 APAP-ASA-IBU Combo Products Limit 1365-H.

OPIOID-3.DOC

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

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

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

If the patient is ≤ 19 years of age and 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, 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 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 APAP-ASA-IBU 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 APAP-ASA-IBU Combo Products Limit 1365-H.

***2888-E will be used 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. 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

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

OPIOID-3.DOC

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

- 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 3 days for moderate to severe ACUTE pain where use of an opioid analgesic is appropriate

Quantity Limits may apply.

REFERENCES

1. Acetaminophen and Codeine Phosphate Solution [package insert]. Amityville, NY: Hi-Tech Pharmacal Co., Inc.; September 2019.
2. Acetaminophen, Caffeine, and Dihydrocodeine Bitartrate Tablet [package insert]. Canton, MS: Larken Laboratories, Inc.; August 2018.
3. Acetaminophen and Codeine Phosphate Tablet [package insert]. Hazelwood, MO: Mallinckrodt Inc.; November 2019.
4. Apadaz [package insert]. Newtown, PA: KVK-Tech, Inc.; September 2019.
5. Aspirin, Caffeine, and Dihydrocodeine [package insert]. Atlanta, GA: Mikart, Inc.; May 2013.
6. Endocet [package insert]. Chestnut Ridge, NY: Par Pharmaceuticals; August 2018.
7. Hycet [package insert]. South Plainfield, NJ: G&W Laboratories, Inc; September 2014.
8. Hydrocodone Bitartrate and Acetaminophen Tablets [package insert]. Brookhaven, NY: Amneal Pharmaceuticals of NY LLC; November 2019.
9. Hydrocodone Bitartrate and Ibuprofen Tablet [package insert]. Brookhaven, NY: Amneal Pharmaceuticals of NY LLC; August 2019.
10. Lortab Elixir [package insert]. Atlanta, GA: Mikart, LLC; November 2018.
11. Nalocet [package insert]. Las Vegas, NV: Forte Bio-Pharma LLC; November 2018.
12. Oxycodone and Acetaminophen Tablet [package insert]. Philadelphia, PA: Lannett Company, Inc; August 2019.
13. Oxycodone and Aspirin [package insert]. Greenville, NC: Mayne Pharma; October 2019.
14. Oxycodone and Ibuprofen [package insert]. Elizabeth, NJ: Actavis Pharma, Inc.; April 2019.
15. Primlev [package insert]. Cranford, NJ: Akrimax Pharmaceuticals, LLC; March 2019.
16. Roxicet Tablet and Solution [package insert]. Columbus, OH: Roxane Laboratories, Inc.; August 2016.
17. Trezix [package insert]. Ridgeland, MS: WraSer Pharmaceuticals LLC; March 2019.
18. Ultracet [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; October 2019.
19. Vicodin [package insert]. North Chicago, IL: AbbVie Inc.; November 2018.
20. Zamiset [package insert]. Greenville, SC: Pharmaceutical Associates, INC; June 2016.
21. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed January 2020.
22. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed January 2020.

OPIOID-3.DOC

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

23. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. *MMWR Recomm Rep* 2016;65:1–49. Available at: <http://dx.doi.org/10.15585/mmwr.rr6501e1>. Accessed January 2020.
24. Palliative Care. NCCN Guidelines version 2.2019. Available at: http://www.nccn.org/professionals/physician_gls/pdf/palliative.pdf. Accessed January 2020.
25. Adult Cancer Pain. NCCN Guidelines version 3.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf. Accessed January 2020.
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%2020816_0.pdf. Accessed January 2020.
27. Gaither, JR, Shabanova V, Leventhal JM. US National Trends in Pediatric Deaths From Prescription and Illicit Opioids, 1999-2016. *JAMA Network Open*. 2018;1(8):e186558.doi:10.1001/jamanetworkopen.2018.6558.
28. Meich R, Johnston L, O'Malley PM, et al. Prescription Opioids in Adolescence and Future Opioid Misuse. *Pediatrics*. 2015 Nov;136(5):e1169-77. doi: 10.1542/peds.2015-1364.

OPIOID-3.DOC

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.