

QUANTITY LIMIT CRITERIA

DRUG CLASS ACETAMINOPHEN/ASPIRIN/IBUPROFEN CONTAINING OPIOID ANALGESICS

(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: Quantity Limit**

***1365-H may be used as a stand-alone criteria OR in combination with Opioids IR Combo Products – Acute Pain Duration Limit 1358-E. The Opioids IR Combo Products – Acute Pain Duration Limit 1358-E 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.

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

Seglantis (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 Seglantis (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.

Opioid Analgesics IR Combo Products Quantity Limits Chart

Coverage is provided without prior authorization for a 30-day or 90-day supply of an immediate-release combination product opioid for a monthly quantity that does not exceed the maximum daily dose listed in product labeling. Quantities also do not exceed 90 MME/day (unless maximum FDA-labeled strength/dose/frequency exceeds 90 MME/day), 4 g/day of acetaminophen or aspirin, or 3200 mg/day of ibuprofen. If the patient is requesting more than the initial quantity limit, then the claim will reject with a message indicating that quantity limits are exceeded.

This quantity limit will accumulate drugs in the following 4 groups up to highest quantity listed in each group depending on the order the claims are processed: 1) Acetaminophen-containing solutions, suspensions, elixirs accumulate together, 2) Acetaminophen-containing tablets and capsules accumulate together, 2a) Acetaminophen-containing tablets with the same 1 month and 3 month limit accumulate together, 3) Aspirin-containing tablets and capsules accumulate together, 4) Ibuprofen-containing tablets accumulate together, 5) Celecoxib-containing tablets accumulate together. See Accumulation Group column in chart below for more detail.

Accumulation Group	Drug/Strength***	Labeled Dosing	Initial 1 Month Limit* ≤ 90 MME/day** and ≤ 4 g APAP or ASA and ≤ 3200 mg IBU	Initial 3 Month Limit* ≤ 90 MME/day** and ≤ 4 g APAP or ASA and ≤ 3200 mg IBU
--------------------	------------------	----------------	---	---

			(per 25 days)	(per 75 days)
1	APAP/codeine soln 120-12 mg/5 mL	q4h, MAX 360 mg codeine/day	2700 mL/month 90 mL/day (32.4 MME/day)	8100 mL/3 months 90 mL/day (32.4 MME/day)
2	APAP/codeine tab 300/15 mg	q4h, MAX 360 mg codeine/day	400 tabs/month 13.34 tabs/day (30 MME/day)	1200 tabs/3 months 13.34 tabs/day (30 MME/day)
2	APAP/codeine tab 300/30 mg	q4h, MAX 360 mg codeine/day	360 tabs/month 12 tabs/day (54 MME/day)	1080 tabs/3 months 12 tabs/day (54 MME/day)
2	APAP/codeine tab 300/60 mg	q4h, MAX 360 mg codeine/day	180 tabs/month 6 tabs/day (54 MME/day)	540 tabs/3 months 6 tabs/day (54 MME/day)
2	APAP/caffeine/dihydrocodeine cap 320.5/30/16 mg	q4h, MAX 10 caps/day	300 caps/month 10 caps/day (40 MME/day)	900 caps/3 months 10 caps/day (40 MME/day)
2	APAP/caffeine/dihydrocodeine tab 325/30/16 mg	q4h, MAX 10 tabs/day	300 tabs/month 10 tabs/day (40 MME/day)	900 tabs/3 months 10 tabs/day (40 MME/day)
2	Benzhydrocodone/APAP 4.08 mg/325 mg	q4-6h, MAX 12 tabs/day for 14 days	168 tabs/month 12 tabs/day (60 MME/day)	Does Not Apply****
2	Benzhydrocodone/APAP 6.12 mg/325 mg	q4-6h, MAX 12 tabs/day for 14 days	168 tabs/month 12 tabs/day (90 MME/day)	Does Not Apply****
2	Benzhydrocodone/APAP 8.16 mg/325 mg	q4-6h, MAX 12 tabs/day for 14 days	168 tabs/month 12 tabs/day (120 MME/day)	Does Not Apply****
5	Celecoxib/Tramadol 56 mg/44 mg	q12h, MAX 4 tabs/day	120 tabs/month 4 tabs/day (15.6 MME/day)	360 tabs/3 months 4 tabs/day (15.6 MME/day)
2	Hydrocodone/APAP tab 2.5/325 mg	q4-6h, MAX 12 tabs/day	360 tabs/month 12 tabs/day (30 MME/day)	1080 tabs/3 months 12 tabs/day (30 MME/day)
2	Hydrocodone/APAP tab 5/300 mg	q4-6h, MAX 8 tabs/day	240 tabs/month 8 tabs/day (40 MME/day)	720 tabs/3 months 8 tabs/day (40 MME/day)
2	Hydrocodone/APAP tab 5/325 mg	q4-6h, MAX 8 tabs/day	240 tabs/month 8 tabs/day (40 MME/day)	720 tabs/3 months 8 tabs/day (40 MME/day)
2	Hydrocodone/APAP tab 7.5/300 mg	q4-6h, MAX 6 tabs/day	180 tabs/month 6 tabs/day (45 MME/day)	540 tabs/3 months 6 tabs/day (45 MME/day)
2	Hydrocodone/APAP tab 7.5/325 mg	q4-6h, MAX 6 tabs/day	180 tabs/month 6 tabs/day (45 MME/day)	540 tabs/3 months 6 tabs/day (45 MME/day)
2	Hydrocodone/APAP tab 10/300 mg	q4-6h, MAX 6 tabs/day	180 tabs/month 6 tabs/day (60 MME/day)	540 tabs/3 months 6 tabs/day (60 MME/day)
2	Hydrocodone/APAP tab 10/325 mg	q4-6h, MAX 6 tabs/day	180 tabs/month 6 tabs/day (60 MME/day)	540 tabs/3 months 6 tabs/day (60 MME/day)

1	Hydrocodone/APAP soln 7.5-325 mg/15 mL (5-217 mg/10 mL)	q4-6h, MAX 90 mL/day	2700 mL/month 90 mL/day (45 MME/day)	8100 mL/3 months 90 mL/day (45 MME/day)
1	Hydrocodone/APAP elixir 10/300 mg/15 mL	q4-6h, MAX 67.5 mL/day	2025 mL/month 67.5 mL/day (45 MME/day)	6075 mL/3 months 67.5 mL/day (45 MME/day)
1	Hydrocodone/APAP soln 10-325 mg/15 mL	q4-6h, MAX 90 mL/day	2700 mL/month 90 mL/day (60 MME/day)	8100 mL/3 months 90 mL/day (60 MME/day)
4	Hydrocodone/ibuprofen tab 5/200 mg	q4-6h, MAX 5 tabs/day for 10 days	50 tabs/month 5 tabs/day (25 MME/day)	Does Not Apply****
4	Hydrocodone/ibuprofen tab 7.5/200 mg	q4-6h, MAX 5 tabs/day for 10 days	50 tabs/month 5 tabs/day (37.5 MME/day)	Does Not Apply****
4	Hydrocodone/ibuprofen tab 10/200 mg	q4-6h, MAX 5 tabs/day for 10 days	50 tabs/month 5 tabs/day (50 MME/day)	Does Not Apply****
1	Oxycodone/APAP soln 5/325 mg/5 mL	q6h, MAX 60 mL/day	1800 mL/month 60 mL/day (90 MME/day)	5400 mL/3 months 60 mL/day (90 MME/day)
1	Oxycodone/APAP soln 10/300 mg/5 mL	q6h, MAX 30 mL/day	900 mL/month 30 mL/day (90 MME/day)	2700 mL/3 months 30 mL/day (90 MME/day)
2	Oxycodone/APAP tab 2.5/300 mg	q6h, MAX 12 tabs/day	360 tabs/month 12 tabs/day (45 MME/day)	1080 tabs/3 months 12 tabs/day (45 MME/day)
2	Oxycodone/APAP tab 2.5/325 mg	q6h, MAX 12 tabs/day	360 tabs/month 12 tabs/day (45 MME/day)	1080 tabs/3 months 12 tabs/day (45 MME/day)
2	Oxycodone/APAP tab 5/300 mg	q6h, MAX 12 tabs/day	360 tabs/month 12 tabs/day (90 MME/day)	1080 tabs/3 months 12 tabs/day (90 MME/day)
2	Oxycodone/APAP tab 5/325 mg	q6h, MAX 12 tabs/day	360 tabs/month 12 tabs/day (90 MME/day)	1080 tabs/3 months 12 tabs/day (90 MME/day)
2	Oxycodone/APAP tab 7.5/300 mg	q6h, MAX 8 tabs/day	240 tabs/month 8 tabs/day (90 MME/day)	720 tabs/3 months 8 tabs/day (90 MME/day)
2	Oxycodone/APAP tab 7.5/325 mg	q6h, MAX 8 tabs/day	240 tabs/month 8 tabs/day (90 MME/day)	720 tabs/3 months 8 tabs/day (90 MME/day)
2	Oxycodone/APAP tab 10/300 mg	q6h, MAX 6 tabs/day	180 tabs/month 6 tabs/day (90 MME/day)	540 tabs/3 months 6 tabs/day (90 MME/day)
2	Oxycodone/APAP tab 10/325 mg	q6h, MAX 6 tabs/day	180 tabs/month 6 tabs/day (90 MME/day)	540 tabs/3 months 6 tabs/day (90 MME/day)
3	Oxycodone/ASA tab 4.8355/325 mg	q6h, MAX 12 tabs/day	360 tabs/month 12 tabs/day (87 MME/day)	1080 tabs/3 months 12 tabs/day (87 MME/day)
4	Oxycodone/ibuprofen tab	q6h, MAX 4 tabs/day for 7 days	28 tabs/month	Does Not Apply****

	5/400 mg		4 tabs/day (30 MME/day)	
2a	Tramadol/APAP 37.5/325 mg	q4-6h, MAX 8 tabs/day for 5 days	40 tabs/month 8 tabs/day (30 MME/day)	Does Not Apply****

*The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing. Limits are set up both as quantity versus time and daily dose edits.

**Unless maximum FDA-labeled strength/dose/frequency exceeds 90 MME/day.

***The limit criteria apply to both brand and generic, if available.

**** This drug is indicated for short-term acute use; therefore, the 30-day limit will be the same as the 90-day limit. The intent is for prescriptions of the requested drug to be filled one month at a time, even if filled at mail order; there should be no 3 month supplies filled.

REFERENCES

1. Acetaminophen and Codeine Phosphate Solution [package insert]. Amityville, NY: Hi-Tech Pharmal Co., Inc.; September 2019.
2. Acetaminophen, Caffeine, and Dihydrocodeine Bitartrate Tablet [package insert]. Canton, MS: Larken Laboratories, Inc.; July 2020.
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. Endocet [package insert]. Chestnut Ridge, NY: Par Pharmaceuticals; August 2020.
6. Hycet [package insert]. South Plainfield, NJ: G&W Laboratories, Inc; September 2014.
7. Hydrocodone Bitartrate and Acetaminophen Tablets [package insert]. Brookhaven, NY: Amneal Pharmaceuticals of NY LLC; November 2019.
8. Hydrocodone Bitartrate and Ibuprofen Tablet [package insert]. Brookhaven, NY: Amneal Pharmaceuticals of NY LLC; August 2019.
9. Lortab Elixir [package insert]. Atlanta, GA: Mikart, LLC; November 2018.
10. Nalocet [package insert]. Las Vegas, NV: Forte Bio-Pharma LLC; November 2018.
11. Oxycodone and Acetaminophen Tablet [package insert]. Philadelphia, PA: Lannett Company, Inc; August 2019.
12. Oxycodone and Aspirin [package insert]. Greenville, NC: Mayne Pharma; July 2020.
13. Oxycodone and Ibuprofen [package insert]. Elizabeth, NJ: Actavis Pharma, Inc.; August 2020.
14. Primlev [package insert]. Cranford, NJ: Akrimax Pharmaceuticals, LLC; March 2019.
15. Prolate [package insert]. Las Vegas, NV: Forte Bio-Pharma LLC; September 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 December 2020.
22. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed December 2020.
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 December 2020.
24. Seglantis [package insert]. Montgomery, AL: Kowa Pharmaceuticals Inc., Inc; October 2021.