Acetaminophen/Aspirin/ Celecoxib/Ibuprofen Containing Immediate Release Opioid Analgesics: Quantity Limit Policy

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242**.**

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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.

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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.

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 Lortab Elixir (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, 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.

Prolate Solution (oxycodone/acetaminophen), Oxycodone/Acetaminophen Solution

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Oxycodone hydrochloride and acetaminophen oral solution is indicated for the 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 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

Seglentis (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

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/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

POLICY

Opioid Analgesics IR Combo Products Quantity Limits

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 5 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

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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 (per 25 days)	Initial 3 Month Limit* ≤ 90 MME/day** and ≤ 4 g APAP or ASA and ≤ 3200 mg IBU (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	Does Not Apply****

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Accumulation Group	Drug/Strength***	Labeled Dosing	Initial 1 Month Limit* ≤ 90 MME/day** and ≤ 4 g APAP or ASA and ≤ 3200 mg IBU (per 25 days)	Initial 3 Month Limit* ≤ 90 MME/day** and ≤ 4 g APAP or ASA and ≤ 3200 mg IBU (per 75 days)
			(120 MME/day)	
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 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)

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Accumulation Group	Drug/Strength***	Labeled Dosing	Initial 1 Month Limit* ≤ 90 MME/day** and ≤ 4 g APAP or ASA and ≤ 3200 mg IBU (per 25 days)	Initial 3 Month Limit* ≤ 90 MME/day** and ≤ 4 g APAP or ASA and ≤ 3200 mg IBU (per 75 days)
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)

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Accumulation Group	Drug/Strength***	Labeled Dosing	Initial 1 Month Limit* ≤ 90 MME/day** and ≤ 4 g APAP or ASA and ≤ 3200 mg IBU (per 25 days)	Initial 3 Month Limit* ≤ 90 MME/day** and ≤ 4 g APAP or ASA and ≤ 3200 mg IBU (per 75 days)
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)
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.*

CLINICAL RATIONALE

The Centers for Disease Control and Prevention (CDC) Clinical Practice Guideline for Prescribing Opioids for Pain provides recommendations for clinicians who are providing pain care, including those prescribing opioids for outpatients aged ≥ 18 years. The recommendations do not apply to pain related to sickle cell disease or cancer or

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to patients receiving palliative or end-of-life care.[24] However, opioid immediate-release (IR) combination products include non-opioid components (acetaminophen, aspirin, and ibuprofen) with established maximum Food and Drug Administration (FDA)-labeled daily doses. FDA-labeled dosing allows for up to a maximum 24-hour dose of 4 grams (4000 mg) of acetaminophen, a maximum 24-hour dose of 4 grams (4000 mg) of aspirin, and a maximum 24-hour dose of 3200 mg of ibuprofen.[1-23] Limits will 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.

The CDC Clinical Practice Guideline for Prescribing Opioids for Pain recommends that when opioids are initiated for opioid-naïve patients, clinicians should prescribe the lowest effective dosage. If opioids are continued, clinicians should use caution when prescribing opioids at any dosage, should carefully evaluate individual benefits and risks when considering increasing dosage, and should avoid increasing dosage above levels likely to yield diminishing returns in benefits relative to risks to patients. Many patients do not experience benefit in pain or function from increasing opioid dosages to ≥ 50 morphine milliequivalents per day (MME/day) but are exposed to progressive increases in risk as dosage increases. Opioid dosages of 50-90 MME/day were associated with a minimally greater improvement in mean pain intensity compared with dosages of < 50 MME/day. Few trials evaluated opioid dosages of ≥ 90 MME/day.[24] The immediate-release opioid combination products initial quantity limits are set for a monthly quantity that does not exceed the maximum daily dose listed in labeling. Monthly quantities also correspond to ≤ 90 MME/day and contain ≤ 4 g/day acetaminophen or aspirin and ≤ 3200 mg/day 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. Quantities above the initial limit are not approved due to the potential for serious adverse effects if the FDA-labeled dosing is exceeded.

For the short-term (no more than 14 days) management of acute pain, the recommended dose of Apadaz (benzhydrocodone/acetaminophen) is 1 to 2 tablets every 4 to 6 hours as needed for pain. Dosage should not exceed 12 tablets in a 24-hour period.[4] Since benzhydrocodone/acetaminophen is only indicated for short-term use, the 1 month and 3 months limits are the same and allow for a quantity sufficient for a 14-day supply (168 tablets).

For the short-term (generally less than 10 days) management of acute pain, the recommended dose of hydrocodone bitartrate/ibuprofen is one tablet every four to six hours, as necessary. Dosages should not exceed five tablets in a 24-hour period.[8] Since hydrocodone bitartrate/ibuprofen is only indicated for short-term use, the 1 month and 3 months limits are the same and allow for a quantity sufficient for a 10-day supply (50 tablets).

For the short-term (five days or less) management of acute pain, the recommended dose of Ultracet (tramadol/acetaminophen) is 2 tablets every 4 to 6 hours as needed for pain relief, up to a maximum of 8 tablets per day.[20] Since tramadol/acetaminophen is only indicated for short-term use, the 1 month and 3 months limits are the same and allow for a quantity sufficient for a 5-day supply (40 tablets).

For the management of acute pain in adults, the recommended dose of Seglentis (tramadol/celecoxib) is 2 tablets every 12 hours as needed for pain. Dosages should not exceed the recommended dose.[18] Therefore, the quantity limit for tramadol/celecoxib will be set at 4 tablets per day.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

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POLICY HISTORY

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