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

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
Acetaminophen/opioid analgesic or aspirin/opioid analgesic combination products
Acetaminophen/opioid analgesic and aspirin/opioid analgesic combination products 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/opioid and aspirin/opioid combination products for use in patients for whom alternative treatment options (e.g., non-opioid analgesics):
  o Have not been tolerated, or are not expected to be tolerated
  o 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

Hydrocodone bitartrate/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 dose 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/ibuprofen
Oxycodone HCl 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) 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
- Ultracet 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 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

Program Description
Coverage is provided without prior authorization for 30-day or 90-day IR opioid combination product prescriptions for a monthly quantity that does not exceed the maximum daily dose listed in product labeling. Quantities also do not exceed 90 MME/day, 4 g/day of APAP or ASA, or 3200 mg/day of ibuprofen. Due to safety concerns for quantities that exceed FDA-labeled dosing recommendations, post limit consideration will not be given.

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.

Opioid Analgesics IR Combo Products Quantity Limits
Coverage is provided without prior authorization for 30-day or 90-day IR opioid combination product prescriptions for a monthly quantity that does not exceed the maximum daily dose listed in product labeling. Quantities also do not exceed 90 MME/day, 4 g/day of APAP or ASA, 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. See Accumulation Group column in chart below for more detail.

<table>
<thead>
<tr>
<th>Accumulation Group</th>
<th>Drug/Strength</th>
<th>Labeled Dosing</th>
<th>Initial 1 Month Limit*</th>
<th>Initial 3 Month Limit*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>APAP/codeine soln 120-12 mg/5 mL</td>
<td>15 mL q4h pm, MAX 360 mg codeine/day</td>
<td>2700 mL (32.4 MME/day)</td>
<td>8100 mL (32.4 MME/day)</td>
</tr>
<tr>
<td>1</td>
<td>APAP/codeine susp 120-12 mg/5 mL</td>
<td>15 mL q4h pm, MAX 360 mg codeine/day</td>
<td>2700 mL (32.4 MME/day)</td>
<td>8100 mL (32.4 MME/day)</td>
</tr>
<tr>
<td>2</td>
<td>APAP/codeine tab 300/15 mg</td>
<td>15-60 mg codeine q4h, MAX 360 mg codeine/day</td>
<td>400 tabs (30 MME/day)</td>
<td>1200 tabs (30 MME/day)</td>
</tr>
<tr>
<td>2</td>
<td>APAP/codeine tab 300/30 mg</td>
<td>15-60 mg codeine q4h, MAX 360 mg codeine/day</td>
<td>360 tabs (54 MME/day)</td>
<td>1080 tabs (54 MME/day)</td>
</tr>
<tr>
<td>2</td>
<td>APAP/codeine tab 300/60 mg</td>
<td>15-60 mg codeine q4h, MAX 360 mg codeine/day</td>
<td>180 tabs (54 MME/day)</td>
<td>540 tabs (54 MME/day)</td>
</tr>
<tr>
<td>2</td>
<td>APAP/caffeine/dihydrocodeine cap 320.5/30/16 mg</td>
<td>2 caps q4h pm, MAX 10 caps/day</td>
<td>300 caps (40 MME/day)</td>
<td>900 caps (40 MME/day)</td>
</tr>
<tr>
<td>2</td>
<td>APAP/caffeine/dihydrocodeine tab 325/30/16 mg</td>
<td>2 tabs q4h pm, MAX 10 tabs/day</td>
<td>300 tabs (40 MME/day)</td>
<td>900 tabs (40 MME/day)</td>
</tr>
<tr>
<td>3</td>
<td>ASA/caffeine/dihydrocodeine cap 356.4/30/16 mg</td>
<td>2 caps q4h pm, MAX 10 caps/day</td>
<td>300 caps (40 MME/day)</td>
<td>900 caps (40 MME/day)</td>
</tr>
<tr>
<td>2</td>
<td>Benzhydrocodone/APAP 4.08 mg/325 mg</td>
<td>1-2 tabs q4-6h, MAX 12 tabs/day</td>
<td>168 tabs (60 MME/day)</td>
<td>168 tabs (60 MME/day)</td>
</tr>
<tr>
<td>2</td>
<td>Benzhydrocodone/APAP 6.12 mg/325 mg</td>
<td>1-2 tabs q4-6h, MAX 12 tabs/day</td>
<td>168 tabs (90 MME/day)</td>
<td>168 tabs (90 MME/day)</td>
</tr>
<tr>
<td>2</td>
<td>Benzhydrocodone/APAP 8.16 mg/325 mg</td>
<td>1-2 tabs q4-6h, MAX 12 tabs/day</td>
<td>168 tabs (120 MME/day)</td>
<td>168 tabs (120 MME/day)</td>
</tr>
<tr>
<td>2</td>
<td>Hydrocodone/APAP tab 2.5/325 mg</td>
<td>1-2 tabs q 4-6h pm, MAX 12 tabs/day</td>
<td>360 tabs (30 MME/day)</td>
<td>1080 tabs (30 MME/day)</td>
</tr>
<tr>
<td>2</td>
<td>Hydrocodone/APAP tab 5/300 mg</td>
<td>1-2 tabs q 4-6h pm, MAX 8 tabs/day</td>
<td>240 tabs (40 MME/day)</td>
<td>720 tabs (40 MME/day)</td>
</tr>
<tr>
<td>Accumulation Group</td>
<td>Drug/Strength</td>
<td>Labeled Dosing</td>
<td>Initial 1 Month Limit*</td>
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</tr>
<tr>
<td>-------------------</td>
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<td>----------------</td>
<td>------------------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>2</td>
<td>Hydrocodone/APAP tab 5/325 mg</td>
<td>1-2 tabs q 4-6h prn, MAX 8 tabs/day</td>
<td>≤ 90 MME/day and ≤ 4 g APAP or ASA and ≤ 3200 mg IBU (per 25 days)</td>
<td>≤ 90 MME/day and ≤ 4 g APAP or ASA and ≤ 3200 mg IBU (per 75 days)</td>
</tr>
<tr>
<td>2</td>
<td>Hydrocodone/APAP tab 7.5/300 mg</td>
<td>1 tab q4-6h, MAX 6 tabs/day</td>
<td>180 tabs (45 MME/day)</td>
<td>540 tabs (45 MME/day)</td>
</tr>
<tr>
<td>2</td>
<td>Hydrocodone/APAP tab 7.5/325 mg</td>
<td>1 tab q4-6h, MAX 6 tabs/day</td>
<td>180 tabs (45 MME/day)</td>
<td>540 tabs (45 MME/day)</td>
</tr>
<tr>
<td>2</td>
<td>Hydrocodone/APAP tab 10/300 mg</td>
<td>1 tab q4-6h, MAX 6 tabs/day</td>
<td>180 tabs (60 MME/day)</td>
<td>540 tabs (60 MME/day)</td>
</tr>
<tr>
<td>2</td>
<td>Hydrocodone/APAP tab 10/325 mg</td>
<td>1 tab q4-6h, MAX 6 tabs/day</td>
<td>180 tabs (60 MME/day)</td>
<td>540 tabs (60 MME/day)</td>
</tr>
<tr>
<td>1</td>
<td>Hydrocodone/APAP soln 7.5/325 mg/15 mL (5-217 mg/10 mL)</td>
<td>15 mL q4-6h prn, MAX 90 mL/day</td>
<td>2700 mL (45 MME/day)</td>
<td>8100 mL (45 MME/day)</td>
</tr>
<tr>
<td>1</td>
<td>Hydrocodone/APAP elixir 10/300 mg/15 mL</td>
<td>11.25 mL q4-6h prn, MAX 67.5 mL/day</td>
<td>2025 mL (45 MME/day)</td>
<td>6075 mL (45 MME/day)</td>
</tr>
<tr>
<td>1</td>
<td>Hydrocodone/APAP soln 10/325 mg/15 mL</td>
<td>15 mL q4-6h prn, MAX 90 mL/day</td>
<td>2700 mL (60 MME/day)</td>
<td>8100 mL (60 MME/day)</td>
</tr>
<tr>
<td>4</td>
<td>Hydrocodone/ibuprofen tab 2.5/200 mg</td>
<td>1 tab q4-6h, MAX 5 tabs/day</td>
<td>50 tabs (12.5 MME/day)</td>
<td>50 tabs (12.5 MME/day)</td>
</tr>
<tr>
<td>4</td>
<td>Hydrocodone/ibuprofen tab 5/200 mg</td>
<td>1 tab q4-6h, MAX 5 tabs/day</td>
<td>50 tabs (25 MME/day)</td>
<td>50 tabs (25 MME/day)</td>
</tr>
<tr>
<td>4</td>
<td>Hydrocodone/ibuprofen tab 7.5/200 mg</td>
<td>1 tab q4-6h, MAX 5 tabs/day</td>
<td>50 tabs (37.5 MME/day)</td>
<td>50 tabs (37.5 MME/day)</td>
</tr>
<tr>
<td>4</td>
<td>Hydrocodone/ibuprofen tab 10/200 mg</td>
<td>1 tab q4-6h, MAX 5 tabs/day</td>
<td>50 tabs (50 MME/day)</td>
<td>50 tabs (50 MME/day)</td>
</tr>
<tr>
<td>1</td>
<td>Oxycodone/APAP soln 5/325 mg/5 mL</td>
<td>5 mL q6h prn, MAX 60 mL/day</td>
<td>1800 mL (90 MME/day)</td>
<td>5400 mL (90 MME/day)</td>
</tr>
<tr>
<td>2</td>
<td>Oxycodone/APAP tab 2.5/300 mg</td>
<td>1-2 tabs q6h, MAX 12 tabs/day</td>
<td>360 tabs (45 MME/day)</td>
<td>1080 tabs (45 MME/day)</td>
</tr>
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<td>Oxycodone/APAP tab 2.5/325 mg</td>
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<td>Oxycodone/APAP tab 5/300 mg</td>
<td>1 tab q6h, MAX 12 tabs/day</td>
<td>360 tabs (90 MME/day)</td>
<td>1080 tabs (90 MME/day)</td>
</tr>
</tbody>
</table>
## CLINICAL RATIONALE

The Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. However, Opioid IR combination products include non-opioid components (acetaminophen, aspirin, and ibuprofen) with established maximum FDA-labeled daily doses. FDA-labeled dosing allows for up to a maximum 24-hour dose of acetaminophen of 4 grams (4000 mg), a maximum 24-hour dose of aspirin of 4 grams (4000 mg), and a maximum 24-hour dose of ibuprofen of 3200 mg. Limits will 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.

The CDC Guideline for Prescribing Opioids for Chronic Pain recommends that when opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing the dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day. 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

### Accumulation Group | Drug/Strength | Labeled Dosing | Initial 1 Month Limit* | Initial 3 Month Limit*  
--- | --- | --- | --- | ---  
2 | Oxycodone/APAP tab 5/325 mg | 1 tab q6h, MAX 12 tabs/day | 360 tabs (90 MME/day) | 1080 tabs (90 MME/day)  
2 | Oxycodone/APAP tab 7.5/300 mg | 1 cap q6h, MAX 8 tabs/day | 240 tabs (90 MME/day) | 720 tabs (90 MME/day)  
2 | Oxycodone/APAP tab 7.5/325 mg | 1 tab q6h prn, MAX 8 tabs/day | 240 tabs (90 MME/day) | 720 tabs (90 MME/day)  
2 | Oxycodone/APAP tab 10/300 mg | 1 tab q6h prn, MAX 6 tabs/day | 180 tabs (90 MME/day) | 540 tabs (90 MME/day)  
2 | Oxycodone/APAP tab 10/325 mg | 1 tab q6h prn, MAX 6 tabs/day | 180 tabs (90 MME/day) | 540 tabs (90 MME/day)  
3 | Oxycodone/ASA tab 4.8355/325 mg | 1 tab q6h prn, MAX 12 tabs/day | 360 tabs (87 MME/day) | 1080 tabs (87 MME/day)  
4 | Oxycodone/ibuprofen tab 5/400 mg | 1 tab q6h, MAX 4 tabs/day | 28 tabs (30 MME/day) | 28 tabs (30 MME/day)  
2a | Tramadol/APAP 37.5/325 mg | 2 tabs q4-6h, MAX 8 tabs/day. Use for 5 days only. | 40 tabs (30 MME/day) | 40 tabs (30 MME/day)  

*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 as quantity versus time edits.  
**Unless maximum FDA-labeled strength/dose/frequency exceeds 90 MME/day.
quantities also correspond to ≤ 90 MME/day and contain ≤ 4 g/day APAP or ASA 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 potential for serious adverse effects if FDA-labeled dosing is exceeded.

For the short-term (generally less than 10 days) management of acute pain, the recommended dosage of all strengths 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. 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 management of acute moderate to severe pain, the recommended dose of oxycodone HCl and ibuprofen is one tablet every 6 hours as needed for pain. Dosage should not exceed 4 tablets in a 24-hour period and should not exceed 7 days. Since oxycodone/ibuprofen is only indicated for short-term use, the 1 month and 3 month limits are the same and allow for a quantity sufficient for a 7-day supply (28 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. Since Ultracet 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 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. Since Apadaz 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).

**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.

**REFERENCES**


POLICY HISTORY

Policy #: 05.02.36
Reviewed: July 2018
Revised: March 2019
Current Effective Date: March 11, 2019