

Reference number(s)

1365-H

# Quantity Limit Immediate-Release Opioid Analgesics

# **Combination Products Limit**

# **Products Referenced by this Document**

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

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.

Brand Name	Generic Name
All brands	acetaminophen and benzhydrocodone
All brands	acetaminophen and codeine
All brands	acetaminophen and hydrocodone
All brands	acetaminophen and oxycodone
All brands	acetaminophen and tramadol
All brands	acetaminophen, caffeine, and dihydrocodeine
All brands	aspirin and oxycodone
All brands	celecoxib and tramadol
All brands	ibuprofen and hydrocodone

# **Indications**

# 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.

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#### **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 or combination products):

- 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.

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#### **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 analysesic 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.

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#### **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 analyseic 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.

# **Quantity Limits May Apply**

# 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 morphine milligram equivalent (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 capsules accumulate together,

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4) Ibuprofen-containing tablets accumulate together, 5) Celecoxib-containing tablets accumulate together. See Accumulation Group column in chart below for more detail.

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.

The initial 1 month and 3 month limits will be 90 MME/day or less unless maximum FDA-labeled strength/dose/frequency exceeds 90 MME/day.

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

For drugs that list "Does Not Apply" in a column, 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; there should be no 3 month supplies filled.

Accumulation Group	Drug/Strength	Labeled Dosing	Initial 1 Month Limit ≤ 90 MME/day and ≤ 4 g acetaminophen or aspirin and ≤ 3200 mg ibuprofen (per 25 days)	Initial 3 Month Limit ≤ 90 MME/day and ≤ 4 g acetaminophen or aspirin and ≤ 3200 mg ibuprofen (per 75 days)
1	acetaminophen/codeine solution 120-12 mg/5 mL	once every 4 hours, 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	acetaminophen/codeine tablets 300/15 mg	once every 4 hours, MAX 360 mg codeine/day	400 tablets/month 13.34 tablets/day (30 MME/day)	1200 tablets/3 months 13.34 tablets/day (30 MME/day)
2	acetaminophen/codeine tablets 300/30 mg	once every 4 hours, MAX 360 mg codeine/day	360 tablets/month 12 tablets/day (54 MME/day)	1080 tablets/3 months 12 tablets/day (54 MME/day)
2	acetaminophen/codeine tablets 300/60 mg	once every 4 hours, MAX 360 mg codeine/day	180 tablets/month 6 tablets/day (54 MME/day)	540 tablets/3 months 6 tablets/day (54 MME/day)
2	acetaminophen/caffeine/ dihydrocodeine cap 320.5/30/16 mg	once every 4 hours, MAX 10 capsules/day	300 capsules/month 10 capsules/day (40 MME/day)	900 capsules/3 months 10 capsules/day (40 MME/day)
2	acetaminophen/caffeine/ dihydrocodeine tablets 325/30/16 mg	once every 4 hours, MAX 10 tablets/day	300 tablets/month 10 tablets/day (40 MME/day)	900 tablets/3 months 10 tablets/day (40 MME/day)

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Accumulation Group	Drug/Strength	Labeled Dosing	Initial 1 Month Limit ≤ 90 MME/day and ≤ 4 g acetaminophen or aspirin and ≤ 3200 mg ibuprofen (per 25 days)	Initial 3 Month Limit ≤ 90 MME/day and ≤ 4 g acetaminophen or aspirin and ≤ 3200 mg ibuprofen (per 75 days)
2	Benzhydrocodone/aceta minophen 4.08 mg/325 mg	once every 4 to 6 hours, MAX 12 tablets/day for 14 days	168 tablets/month 12 tablets/day (60 MME/day)	Does Not Apply
2	Benzhydrocodone/aceta minophen 6.12 mg/325 mg	once every 4 to 6 hours, MAX 12 tablets/day for 14 days	168 tablets/month 12 tablets/day (90 MME/day)	Does Not Apply
2	Benzhydrocodone/aceta minophen 8.16 mg/325 mg	once every 4 to 6 hours, MAX 12 tablets/day for 14 days	168 tablets/month 12 tablets/day (120 MME/day)	Does Not Apply
5	Celecoxib/Tramadol (Seglentis) 56 mg/44 mg	once every 12 hours, MAX 4 tablets/day	120 tablets/month 4 tablets/day (35.2 MME/day)	360 tablets/3 months 4 tablets/day (35.2 MME/day)
2	Hydrocodone/acetamino phen tablets 2.5/325 mg	once every 4 to 6 hours, MAX 8 tablets/day	240 tablets/month 8 tablets/day (20 MME/day)	720 tablets/3 months 8 tablets/day (20 MME/day)
2	Hydrocodone/acetamino phen tablets 5/300 mg	once every 4 to 6 hours, MAX 8 tablets/day	240 tablets/month 8 tablets/day (40 MME/day)	720 tablets/3 months 8 tablets/day (40 MME/day)
2	Hydrocodone/acetamino phen tablets 5/325 mg	once every 4 to 6 hours, MAX 8 tablets/day	240 tablets/month 8 tablets/day (40 MME/day)	720 tablets/3 months 8 tablets/day (40 MME/day)
2	Hydrocodone/acetamino phen tablets 7.5/300 mg	once every 4 to 6 hours, MAX 6 tablets/day	180 tablets/month 6 tablets/day (45 MME/day)	540 tablets/3 months 6 tablets/day (45 MME/day)
2	Hydrocodone/acetamino phen tablets 7.5/325 mg	once every 4 to 6 hours, MAX 6 tablets/day	180 tablets/month 6 tablets/day (45 MME/day)	540 tablets/3 months 6 tablets/day (45 MME/day)

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Accumulation Group	Drug/Strength	Labeled Dosing	Initial 1 Month Limit ≤ 90 MME/day and ≤ 4 g acetaminophen or aspirin and ≤ 3200 mg ibuprofen (per 25 days)	Initial 3 Month Limit ≤ 90 MME/day and ≤ 4 g acetaminophen or aspirin and ≤ 3200 mg ibuprofen (per 75 days)
2	Hydrocodone/acetamino phen tablets 10/300 mg	once every 4 to 6 hours, MAX 6 tablets/day	180 tablets/month 6 tablets/day (60 MME/day)	540 tablets/3 months 6 tablets/day (60 MME/day)
2	Hydrocodone/acetamino phen tablets 10/325 mg	once every 4 to 6 hours, MAX 6 tablets/day	180 tablets/month 6 tablets/day (60 MME/day)	540 tablets/3 months 6 tablets/day (60 MME/day)
1	Hydrocodone/acetamino phen solution 7.5-325 mg/15 mL (5-217 mg/10 mL)	once every 4 to 6 hours, 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/acetamino phen (Lortab Elixir) 10/300 mg/15 mL	once every 4 to 6 hours, 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/acetamino phen solution 10-325 mg/15 mL	once every 4 to 6 hours, 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 tablets 5/200 mg	once every 4 to 6 hours, MAX 5 tablets/day for 10 days	50 tablets/month 5 tablets/day (25 MME/day)	Does Not Apply
4	Hydrocodone/ibuprofen tablets 7.5/200 mg	once every 4 to 6 hours, MAX 5 tablets/day for 10 days	50 tablets/month 5 tablets/day (37.5 MME/day)	Does Not Apply
4	Hydrocodone/ibuprofen tablets 10/200 mg	once every 4 to 6 hours, MAX 5 tablets/day for 10 days	50 tablets/month 5 tablets/day (50 MME/day)	Does Not Apply
1	Oxycodone/acetaminoph en solution 5/325 mg/5 mL	once every 6 hours, MAX 60 mL/day	1800 mL/month 60 mL/day (90 MME/day)	5400 mL/3 months 60 mL/day (90 MME/day)

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Accumulation Group	Drug/Strength	Labeled Dosing	Initial 1 Month Limit ≤ 90 MME/day and ≤ 4 g acetaminophen or aspirin and ≤ 3200 mg ibuprofen (per 25 days)	Initial 3 Month Limit ≤ 90 MME/day and ≤ 4 g acetaminophen or aspirin and ≤ 3200 mg ibuprofen (per 75 days)
1	Oxycodone/acetaminoph en solution 10/300 mg/5 mL	once every 6 hours, 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/acetaminoph en tablets 2.5/300 mg	once every 6 hours, MAX 12 tablets/day	360 tablets/month 12 tablets/day (45 MME/day)	1080 tablets/3 months 12 tablets/day (45 MME/day)
2	Oxycodone/acetaminoph en tablets 2.5/325 mg	once every 6 hours, MAX 12 tablets/day	360 tablets/month 12 tablets/day (45 MME/day)	1080 tablets/3 months 12 tablets/day (45 MME/day)
2	Oxycodone/acetaminoph en tablets 5/300 mg	once every 6 hours, MAX 12 tablets/day	360 tablets/month 12 tablets/day (90 MME/day)	1080 tablets/3 months 12 tablets/day (90 MME/day)
2	Oxycodone/acetaminoph en tablets 5/325 mg	once every 6 hours, MAX 12 tablets/day	360 tablets/month 12 tablets/day (90 MME/day)	1080 tablets/3 months 12 tablets/day (90 MME/day)
2	Oxycodone/acetaminoph en tablets 7.5/300 mg	once every 6 hours, MAX 8 tablets/day	240 tablets/month 8 tablets/day (90 MME/day)	720 tablets/3 months 8 tablets/day (90 MME/day)
2	Oxycodone/acetaminoph en tablets 7.5/325 mg	once every 6 hours, MAX 8 tablets/day	240 tablets/month 8 tablets/day (90 MME/day)	720 tablets/3 months 8 tablets/day (90 MME/day)
2	Oxycodone/acetaminoph en tablets 10/300 mg	once every 6 hours, MAX 6 tablets/day	180 tablets/month 6 tablets/day (90 MME/day)	540 tablets/3 months 6 tablets/day (90 MME/day)
2	Oxycodone/acetaminoph en tablets 10/325 mg	once every 6 hours, MAX 6 tablets/day	180 tablets/month 6 tablets/day (90 MME/day)	540 tablets/3 months 6 tablets/day (90 MME/day)

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Accumulation Group	Drug/Strength	Labeled Dosing	Initial 1 Month Limit ≤ 90 MME/day and ≤ 4 g acetaminophen or aspirin and ≤ 3200 mg ibuprofen (per 25 days)	Initial 3 Month Limit ≤ 90 MME/day and ≤ 4 g acetaminophen or aspirin and ≤ 3200 mg ibuprofen (per 75 days)
3	Oxycodone/aspirin tablets 4.8355/325 mg	once every 6 hours, MAX 12 tablets/day	360 tablets/month 12 tablets/day (87 MME/day)	1080 tablets/3 months 12 tablets/day (87 MME/day)
2a	Tramadol/acetaminophe n 37.5/325 mg	once every 4 to 6 hours, MAX 8 tablets/day for 5 days	40 tablets/month 8 tablets/day (60 MME/day)	Does Not Apply

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