Opioids IR Quantity Limit Program Summary

This program applies to FlexRx Open, FlexRx Closed, GenRx Open, GenRx Closed, Medicaid, Health Insurance Marketplace, FocusRx and KeyRx formularies.

This is a FlexRx standard and GenRx standard program.

FDA APPROVED INDICATIONS:[1-14, 16-17]

Agent	Strength	Dosing
butorphanol nasal spray[a]	Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.	The usual recommended initial dose is 1 mg (1 spray in one nostril). If adequate pain relief is not achieved within 60 to 90 minutes, an additional 1 mg dose may be given. The initial dose sequence outlined above may be repeated in 3 to 4 hours as required after the second dose of the sequence. Depending on the severity of the pain, an initial dose of 2 mg (1 spray in each nostril) may be used in patients who will be able to remain recumbent in the event drowsiness or dizziness occurs. In such patients, single additional 2 mg doses should not be given for 3 to 4 hours.
codeine[a] tablet	Management of mild to moderate pain, where treatment with an opioid is appropriate and for which alternative treatments are inadequate.	15 mg to 60 mg repeated up to every four hours as needed for pain. The maximum 24 hour dose is 360 mg.
Dilaudid[a] (hydromorphone) tablet, liquid	Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.	Every 4-6 hours
Levorphanol[a] tablet	management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.	Every 6-8 hours

Agent	Strength	Dosing
Demerol[a] (meperidine) tablet, solution	Management of pain, severe enough to require an opioid analgesic and for which alternative treatments are inadequate.	Every 3-4 hours
Dolophine[a], Methadose[a] (methadone) tablet, soluble tablet, solution	Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate	Every 8-12 hours
morphine[a] tablet, concentrate, solution	Management of acute and chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.	Every 4 hours
Oxaydo (oxycodone) tablet	Management of acute and chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.	Every 4-6 hours
oxycodone[a] tablet, solution, concentrate	Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.	Every 4-6 hours
Roxicodone[a] (oxyc odone) tablet	Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.	Every 4-6 hours
Roxybond (oxycodone) tablet	Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.	Every 4-6 hours
Opana[a] (oxymorphone) tablet	Management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.	Every 4-6 hours
Nucynta (tapentadol) tablet	Management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.	Every 4-6 hours. Daily doses greater than 700 mg on the first day of therapy and 600 mg on subsequent days have not been studied and are not recommended.

Agent	Strength	Dosing
Ultram[a] (tramadol) tablet	Management of pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate.	Every 4 to 6 hours not to exceed 400 mg/day

a – generic available

Use of tramadol or codeine containing products in pediatric patients has cause life-threatening respiratory depression, with some of the reported cases occurring post-tonsillectomy and/or adenoidectomy. Ultra-rapid metabolizers are at increased risk of life-threatening respiratory depression due to a CYP2D6 polymorphism. Use in children under 12 years of age is contraindicated for these products, and for those between the ages of 12 and 18 years when used for post-operative pain management following tonsillectomy and/or adenoidectomy.[15]

REFERENCES

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Opioids IR Quantity Limit

OBJECTIVE
The intent of the Opioids IR quantity limit is to encourage FDA approved dosing regimen. Requests for larger quantities will be approved upon review.

QUANTITY LIMIT TARGET AGENTS – RECOMMENDED LIMITS

Agent	Strength	GPI	Brand (B)/ Generic (G) Availability	Daily Quantity Limit
butorphanol	10 mg/mL nasal spray	65200020102050	G	2.9167 mL
Codeine	15 mg tablet	65100020200305	B	6 tablets
Codeine	30 mg tablet	65100020200310	BG	6 tablets
Codeine	60 mg tablet	65100020200315	B	6 tablets
Dilaudid (hydromorphone)	2 mg tablet	65100035100310	BG	6 tablets
Dilaudid (hydromorphone)	4 mg tablet	65100035100320	BG	6 tablets
Dilaudid (hydromorphone)	8 mg tablet	65100035100330	BG	6 tablets
Dilaudid (hydromorphone)	1 mg/mL liquid	65100035100920	BG	48 mL
Levorphanol	2 mg tablet	65100040100305	G	4 tablets
Levorphanol	3 mg tablet	65100040100310	B	4 tablets
meperidine	50 mg tablet	65100045100305	G	8 tablets
Demerol (meperidine)	100 mg tablet	65100045100310	BG	8 tablets
Meperidine	50 mg/5 mL solution	65100045102060	B	80 mL
Dolophine (methadone)	5 mg tablet	65100050100305	BG	3 tablets
Dolophine (methadone)	10 mg tablet	65100050100310	BG	3 tablets
Methadose (methadone	40 mg soluble tablet	65100050107320	G	3 tablets
methadone	5 mg/5mL solution	65100050102010	BG	30 mL
methadone	10 mg/5 mL solution	65100050102015	BG	15 mL
methadone	10 mg/mL concentrate	65100050101310	BG	3 mL
Morphine	15 mg tablet	65100055100310	B	8 tablets
Morphine	30 mg tablet	65100055100315	B	6 tablets
Morphine	10 mg/5 mL solution	65100055102065	G	90 mL
Morphine	20 mg/5 mL solution	65100055102070	G	45 mL
Morphine	20 mg/mL concentrate	65100055102090	G	9 mL

Agent	Strength	GPI	Brand (B)/ Generic (G) Availability	Daily Quantity Limit
oxycodone	5 mg capsule	65100075100110	G	12 capsules
Oxaydo, Roxybond (oxycodone)	5 mg tablet	6510007510A510	B	6 tablets
Oxaydo (oxycodone)	7.5 mg tablet	6510007510A520	B	6 tablets
oxycodone	10 mg tablet	65100075100320	G	6 tablets
oxycodone	20 mg tablet	65100075100330	G	6 tablets
oxycodone	5 mg/5mL solution	65100075102005	G	180 mL
oxycodone	20 mg/mL concentrate	65100075101320	G	9 mL
Roxicodone (oxycodone)	5 mg tablet	65100075100310	BG	12 tablets
Roxyicodone (oxycodone)	15 mg tablet	65100075100325	BG	6 tablets
Roxybond (oxycodone)	15 mg tablet	6510007510A540	B	6 tablets
Roxybond (oxycodone)	30 mg tablet	6510007510A560	B	6 tablets
Roxicodone (oxycodone)	30 mg tablet	65100075100340	BG	6 tablets
Opana (oxymorphone)	5 mg tablet	65100080100305	BG	6 tablets
Opana (oxymorphone)	10 mg tablet	65100080100310	BG	6 tablets
Nucynta (tapentadol)	50 mg tablet	65100091100320	B	6 tablets
Nucynta (tapentadol)	75 mg tablet	65100091100330	B	6 tablets
Nucynta (tapentadol)	100 mg tablet	65100091100340	B	6 tablets
Ultram (tramadol)	50 mg tablet	65100095100320	BG	8 tablets

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Quantities of **Opioid IR agents** above the program set limit but **less than or equal to the Program Maximum Daily Dose** (maximum mg allowed with highest dosage strength) will be approved when ALL of the following are met:

1. The quantity (dose) requested cannot be achieved using a lesser quantity of a higher strength
   AND
2. The prescriber has submitted documentation in support of therapy with a higher dose (quantity) for the intended diagnosis
   AND
3. ONE of the following:
   a. The requested opioid does not contain tramadol or codeine
      OR

b. The requested opioid contains tramadol or codeine AND ONE of the following:
    i. The patient is between 12 and 18 years of age AND the requested opioid will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy
    OR
    ii. The patient is 18 years of age or older

Length of Approval: 1 month for dose titration requests and
Up to 6 months for all other requests

Quantities of **Opioids IR agents** which are **greater than the Program Maximum Daily Dose** (maximum mg allowed with highest dosage strength) will be approved when ALL of the following are met:

1. The quantity (dose) requested cannot be achieved using a lesser quantity of a higher strength
   AND
2. ONE of the following:
    a. The member has a diagnosis of active cancer pain due to an active malignancy
    OR
    b. The member is eligible for hospice care
    OR
    c. The member is undergoing treatment of pain and ALL of the following are met:
        i. The prescriber provides documentation of a formal, consultative evaluation including:
            1. Diagnosis
            AND
            2. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy
            AND
            3. The need for continued opioid therapy has been assessed
        AND
        ii. The prescriber has confirmed that a patient-specific pain management plan is on file for the patient
        AND
        iii. The prescriber has confirmed that the patient is not diverting the requested medication, according to the patient's records in the state's prescription drug monitoring program (PDMP), if applicable

   AND
3. The prescriber has submitted documentation in support of therapy with a higher dose (quantity) for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist.
   AND
4. ONE of the following:
    a. The requested opioid does not contain tramadol or codeine
    OR

b. The requested opioid contains tramadol or codeine AND ONE of the following:
    i. The patient is between 12 and 18 years of age AND the requested opioid will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy **OR**
    ii. The patient is 18 years of age or older

Length of Approval: 1 month for dose titration requests
Up to 6 months for all other requests