Opioid Analgesic/Opioid Combination Products

Override(s)	Approval Duration
Quantity Limit	Initial request: 3 months Maintenance Therapy: Additional authorization required every 6 months Individuals receiving for terminal diagnosis and receiving palliative care/end-of-life therapy: Lifetime Individuals receiving for cancer related pain: 1 year

Generic Name	Brand Name	Quantity Limit
APAP/Caf/Dihydrocodeine 320.5mg/30mg/16mg	Trezix	6 capsules per day*
APAP/Caf/Dihydrocodeine 325mg/30mg/16mg	N/A	6 tablets per day
APAP/codeine 300mg/15mg	N/A	6 tablets per day
APAP/codeine 300mg/30mg*	N/A	6 tablets per day
APAP/codeine 300mg/60mg*	N/A	6 tablets per day
APAP/codeine Suspension or Elixir 120mg-12mg/5mL	N/A	30mL per day*
Benzhydrocodone/APAP 4.08/325mg, 6.12mg/325mg, 8.16/325mg	Apadaz	6 tablets per day
Butalbital/APAP/Caffeine/Codeine 50/300/40/30mg	Fioricet with Codeine	6 capsules per day
Butalbital/APAP/Caffeine/Codeine 50/325/40/30mg	N/A	6 capsules per day
Butalbital/ASA/Caffeine/Codeine 50/325/40/30mg	Ascomp with Codeine, Fiorinal with Codeine	6 capsules per day
Butorphanol nasal spray	Stadol Nasal Spray	2 bottles per 30 days
Codeine sulfate 15 mg, 30 mg	N/A	6 tablets per day
Codeine sulfate 60 mg*	N/A	6 tablets per day
Hydrocodone/APAP 7.5-325mg/15mL	N/A	90 mL per day*
Hydrocodone/APAP 10-325mg/15mL	N/A	90 mL per day*
Hydrocodone/APAP 10-300mg/15mL	Lortab Solution	67.5 mL per day*
Hydrocodone/APAP 5/300 mg, 7.5mg/300 mg, 10/300 mg	N/A	6 tablets per day
Hydrocodone/APAP 2.5/325mg, 5/325 mg, 7.5/325 mg, 10/325 mg	Lorcet, Lorcet HD, Lorcet Plus, Norco	6 tablets per day

Hydrocodone/Ibuprofen 5/200 mg, 7.5/200 mg, 10/200 mg	Ibudone	5 tablets per day AND 50 tablets per fill*; treatment should not exceed 10 days
Hydromorphone 2 mg, 4 mg	Dilaudid	6 tablets per day
Hydromorphone 8 mg	Dilaudid	6 tablets per day
Hydromorphone suppository 3 mg	Dilaudid	4 suppositories per day
Hydromorphone oral liquid 1 mg/mL	Dilaudid	24 mL per day
Meperidine 100 mg	Demerol	6 tablets per day
Meperidine 50 mg	Demerol	6 tablets per day
Meperidine oral 50 mg/mL	Demerol	30 mL per day
Morphine sulfate IR 15mg, 30mg	MS IR	6 tablets per day
Morphine sulfate rectal suppositories 5 mg, 10 mg, 20 mg, 30 mg	Morphine	6 suppositories per day
Morphine sulfate solution 20mg/5mL	Morphine	30 mL per day
Morphine sulfate 20mg/mL Oral Syringe, 100 mg/5 mL solution	Morphine	6 mL per day
Nalbuphene injection 10mg/mL, 20mg/mL	Nubain	2 mL per day
Oxycodone 5 mg	Roxicodone, Roxybond	6 tablets per day
Oxycodone 5 mg	OxylR 5 mg	6 capsules per day
Oxycodone 10mg	N/A	6 tablets per day
Oxycodone 15 mg	Roxicodone, Roxybond	6 tablets per day
Oxycodone 20mg	N/A	6 tablets per day
Oxycodone 30 mg	Roxicodone, Roxybond	6 tablets per day
Oxycodone 5mg, 7.5mg	Oxaydo 5 mg, 7.5 mg	6 tablets per day
Oxycodone concentrate 20mg/mL	N/A	6 mL per day
Oxycodone solution 5mg/5mL	N/A	30 mL per day
Oxycodone oral syringe 10mg/0.5 mL	N/A	6 mL per day
Oxycodone/APAP 2.5/325 mg, 5/325 mg, 7.5/325 mg, 10/325 mg	Endocet, Percocet, Roxicet	6 tablets per day
Oxycodone/APAP 2.5/300mg, 5/300 mg, 7.5/300 mg, 10/300 mg	Nalocet, Prolate	6 tablets per day
Oxycodone/APAP 5mg-325mg/5mL, 10-300mg/5mL solution	Prolate Solution	30 mL per day
Oxycodone/IBU	Combunox	4 tabs/day AND 28 tablets per fill*
Oxymorphone 5mg, 10mg	Opana	6 tablets per day
Pentazocine/naloxone 50/0.5mg	N/A	6 tablets per day
Tapentadol HCl 50mg*	Nucynta	181 tablets per 30 days

Tapentadol HCl 75 mg*	Nucynta	242 tablets per 30 days
Tapentadol HCl 100mg	Nucynta	181 tablets per 30 days
Tramadol Oral Solution 5mg/mL*	Qdolo	80 mL per day
Tramadol 25mg*	N/A	16 tablets per day
Tramadol 50mg*	Ultram	8 tablets per day
Tramadol 75mg*	N/A	5 tablets per day
Tramadol 100mg*	N/A	4 tablets per day
Tramadol/APAP 37.5/325mg	Ultracet	8 tablets per day AND 40 tablets per fill*; treatment should not exceed 5 days.
Celecoxib/Tramadol 56/44mg	Seglentis	4 tablets per day*

*Indicates FDA maximum recommended dose for specific drug and dosage strength

APPROVAL CRITERIA

For approval of increased quantities of opioid/non-opioid analgesic combination agents, the following criteria must be met (NOTE: if individual meets criteria below, approve up to the FDA maximum approved dose):

I. Individual has been diagnosed with cancer and appropriate cancer pain management requires dosing that exceeds the restricted amount; **OR**

II. Individual has a terminal illness and appropriate pain management requires dosing that exceeds the restricted amount;

OR

III. Individual meets one of the following:
   A. Individual is stabilized on current dose and opioid utilization at that dose is effective in reducing pain and/or increasing function; **OR**
   B. Individual has obtained partial pain relief at lower doses of opioids and dose escalation is clinically appropriate;

AND

IV. Individual will be routinely monitored regarding continued improvement in pain and/or function as well as the absence of aberrant behaviors (including but not limited to: obtaining prescriptions from other providers, obtaining opioids from non-medical sources, forgery/alteration of prescriptions, recurrent episodes of prescription loss or theft, recurrent episodes of running short of medication supply and/or repeated requests for early refills). (AMDG 2015)

NOTE: It may be possible in some instances to use a higher strength of the requested medication and take fewer tablets/capsules to achieve the same total daily dosage requested.

FDA maximum quantity limits are based on the label or FDA maximum dose of non-opioid component as noted below:

I. Acetaminophen: 4000mg per day.
II. Aspirin: 4000mg per day.
III. Codeine: 360mg per day.
IV. Oxycodone/Ibuprofen: 4 tablets per day AND 28 tablets /fill.
V. Tramadol/acetaminophen: 8 tablets per day; treatment should not exceed 5 days.
VI. Hydrocodone/ibuprofen: 5 tablets per day; treatment should not exceed 10 days.
VII. Seglentis (celecoxib/tramadol): 4 tablets per day.

For approval of increased quantities of select single agent short-acting opioid analgesics**,** the following criteria must be met:

I. Individual has been diagnosed with cancer and appropriate cancer pain management requires dosing that exceeds the restricted amount; **OR**
II. Individual has a terminal illness and appropriate pain management requires dosing that exceeds the restricted amount;

OR

III. Individual meets one of the following:
   C. Individual is stabilized on current dose and opioid utilization at that dose is effective in reducing pain and/or increasing function; **OR**
   D. Individual has obtained partial pain relief at lower doses of opioids and dose escalation is clinically appropriate;

AND

IV. Individual will be routinely monitored regarding continued improvement in pain and/or function as well as the absence of aberrant behaviors (including but not limited to: obtaining prescriptions from other providers, obtaining opioids from non-medical sources, forgery/alteration of prescriptions, recurrent episodes of prescription loss or theft, recurrent episodes of running short of medication supply and/or repeated requests for early refills). (AMDG 2015)

NOTE: It may be possible in some instances to use a higher strength of the requested medication and take fewer tablets/capsules to achieve the same total daily dosage requested.

For the following opioid agents that have a maximum FDA-approved dosing, quantity limits are assigned based on FDA-approved maximum adult daily dose:

I. Tramadol: 400 mg per day.
II. Nucynta (tapentadol) immediate-release: 700 mg per day on day 1, 600mg per day thereafter.

Tramadol Agents may be subject to the following age requirements via prior authorization:

I. Individual is 18 years of age or older; **OR**
II. Individual is 12 years of age or older and treating for pain conditions other than post-surgical removal of tonsils and/or adenoids. (FDA Safety Announcement 2017)

NOTE: An FDA Safety advisory released on 4-20-2017 noted that the label for tramadol containing agents would be updated to include the following contraindications: contraindication for use in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids, and contraindication for use in treating pain in children younger than 12 years. This is due to serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years (https://www.fda.gov/drugs/drugsafety/ucm549679.htm).

Codeine Agents for pain (such as, acetaminophen with codeine or single agent codeine agents) may be subject to the following age requirements via prior authorization:

I. Individual is 12 years of age or older. (FDA Safety Announcement 2017)

NOTE: An FDA Safety advisory released on 4-20-2017 noted that the label for codeine containing agents would be updated to include a contraindication for use in treating pain or cough in children younger than 12 years. This is due to serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years (https://www.fda.gov/drugs/drugsafety/ucm549679.htm).

Key References:

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4. Advanced Opioid Converter. GlobalRPh.com [Internet database]. URL: http://www.globalrph.com/opioidconverter2.htm.
5. American Society of Interventional Pain Physicians (07/2012). "American Society of Interventional Pain Physicians (ASIPP) guidelines for responsible opioid prescribing in chronic non-cancer pain: Part 2--guidance". Pain physician (1533-3159), 15 (3 suppl), p. S67.
6. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2022. MMWR Recomm Rep 2016;65:1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1.
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10. VA/DOD Clinical Practice Guideline for Opioid Therapy for Chronic Pain. Department of Veterans Affairs/Department of Defense. Version 3.0 – 2017. Available from: https://www.healthquality.va.gov/guidelines/Pain/cot/VADoDOTCPG022717.pdf.
11. VA/DoD Clinical Practice Guideline. (2022). Use of Opioids in the Management of Chronic Pain Work Group. Washington, DC: U.S. Government Printing Office.
12. Washington State Agency Medical Directors' Group. Interagency guideline on opioid dosing for chronic non-cancer pain: an educational aid to improve care and safety with opioid treatment. Olympia (WA): Washington State Department of

Labor and Industries; June 2015. Available from: http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf
13. US Food and Drug Administration. FDA Drug Safety Communication: FDA requires labeling changes for prescription opioid cough and cold medicines to limit their use to adults 18 years and older. January 11, 2018. Available from: https://www.fda.gov/Drugs/DrugSafety/ucm590435.htm.
14. FDA Drug Safety Communication: FDA restricts use of prescription codeine pain and cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women. U.S. Food and Drug Administration. 4-20-2017. Available from: https://www.fda.gov/drugs/drugsafety/ucm549679.htm.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.