

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Opioid Analgesic/Opioid Combination Products

Override(s)	Approval Duration
Quantity Limit	1 year

Generic Name	Brand Name	Quantity Limit
APAP/Caf/Dihydrocodeine 320.5mg/30mg/16mg	Trezix (new formulation)	6 capsules per day
APAP/Caf/Dihydrocodeine 325mg/30mg/16mg	N/A	6 tablets per day
ASA/Caf/Dihydrocodeine 356mg/30mg/16mg	Synalgos-DC	6 capsules per day
APAP/codeine 300mg/15mg	Tylenol with Codeine	6 tablets per day
APAP/codeine 300mg/30mg	Tylenol with Codeine	6 tablets per day
APAP/codeine 300mg/60mg	Tylenol with Codeine	6 tablets per day
APAP/codeine Suspension or Elixir 120mg- 12mg/5mL, 300mg-30mg/12.5mL	Capital with Codeine	30mL per day
Buprenorphine HCl ampule 0.3 mg/mL	Buprenex	3 mL per day
Buprenorphine HCl syringe/vial 0.3 mg/mL	N/A	3 mL 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 1 mg/mL injection	Stadol	8 mL per day
Butorphanol 2 mg/mL injection	Stadol	4 mL 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	Hycet	90 mL per day
Hydrocodone/APAP 10-325mg/15mg	Zamicet	90 mL per day
Hydrocodone/APAP 10-300mg/15mL	Lortab Solution	67.5 mL per day
Hydrocodone/APAP 2.5-108mg/5mL	N/A	30 mL per day
Hydrocodone/APAP 5-163 mg/7.5 mL	N/A	45 mL per day
Hydrocodone/APAP 5-217mg/10mL	N/A	60 mL per day

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Hydrocodone/APAP 5/300 mg, 7.5mg/300 mg, 10/300 mg	Vicodin, Vicodin ES, Vicodin HP, Xodol	6 tablets per day
Hydrocodone/APAP 2.5/325mg, 5/325 mg, 7.5/325 mg, 10/325 mg	Lorcet, Lorcet HD, Lorcet Plus, Lortab, Norco, Verdocet	6 tablets per day
Hydrocodone/Ibuprofen 2.5/200 mg, 5/200 mg, 7.5/200 mg, 10/200 mg	Ibudone, Reprexain, Vicoprofen, Xylone	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
Hydromorphone injection 10 mg/mL	Dilaudid-HP	1 injection per 30 days
Hydromorphone injection 0.5 mg/0.5mL syringe (including PF), 1 mg/mL ampule/syringe (including PF), 2 mg/mL ampule/syringe/vial (including PF)	Dilaudid	6 mL per day
Hydromorphone injection 4 mg/mL ampule/syringe (including PF)	Dilaudid	2 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
Meperidine injection 10 mg/mL, 25 mg/mL, 50 mg/mL, 75 mg/mL, 100 mg/mL, 100 mg/2mL, 75 mg/1.5mL	Demerol	4 mL per day
Morphine sulfate IR 15mg, 30mg	MS IR	6 tablets per day
Morphine (pf) injection solution 0.5 mg/mL, 1 mg/mL	Astramorph-PF	6 mL per day
Morphine injection 0.5 mg/mL, 1 mg/mL	Duramorph	6 mL per day
Morphine sulfate injection 10mg/0.7 mL	Morphine	6 injections/pens per day

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Morphine sulfate injection 0.5 mg/1 mL, 2 mg/mL (10 mg/5 mL), 4 mg/mL, 5 mg/mL, 8 mg/mL, 10mg/mL (15 mg/1.5 mL)	Morphine	6 mL per day
Morphine sulfate injection 10 mg/mL (200mg/20 mL)	Duramorph, Mitigo	4 mL per day
Morphine sulfate injection 15 mg/mL, 25 mg/mL (100 mg/4 mL, 250 mg/10 mL, 500mg/20 mL)	Morphine, Mitigo	4 mL per day
Morphine sulfate injection 50 mg/mL	Morphine	2 mL per day
Morphine sulfate solution 10mg/5mL	Morphine	30 mL per day
Morphine sulfate injection 150mg/30mL	Morphine	1 vial (30 mL) 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 10 mg/0.5 mL injection	Oxycodone	2 mL 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 7.5/500 mg	Percocet	6 tablets per day
Oxycodone/APAP 10/500 mg tablet	Xolox	6 tablets 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, Primlev	6 tablets per day
Oxycodone/APAP 5/500 mg capsule	Tylox	6 capsules per day

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Oxycodone/APAP 5-325mg/5mL solution	Roxicet Solution	30 mL per day
Oxycodone/APAP 7.5/325 mg extended-release	Xartemis XR	4 tablets per day
Oxycodone/ASA 5/325 mg (4.8355/325mg)	Endodan, Percodan	6 tablets per day
Oxycodone/IBU	Combunox	4 tabs/day AND 28 tablets per fill
Oxymorphone 5mg, 10mg	Opana	6 tablets per day
Pentazocine	Talwin 30 mg/mL	12 mL 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 50mg	Ultram	8 tablets per day
Tramadol/APAP 37.5/325mg	Ultracet	8 tablets per day AND 40 tablets per fill; treatment should not exceed 5 days.

APPROVAL CRITERIA

For approval of increased quantities of opioid/non-opioid analgesic combination agents, the following criteria must be met:

- I. Individual has one of the following:
 - A. A diagnosis of cancer related pain; **OR**
 - B. A terminal condition and is receiving palliative/end-of-life care; **OR**
- II. Individual has a severe pain condition requiring higher daily doses (NOTE: approve up to the FDA maximum approved dose).

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.

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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

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

- I. Individual has one of the following:
 - A. A diagnosis of cancer related pain; **OR**
 - B. A terminal condition and is receiving palliative/end-of-life care; **OR**
- II. Individual has a severe pain condition requiring higher daily doses.

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
- III. Talwin injection (pentazocine): 360 mg per day

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

- I. Individual is 18 years of age or older; **OR**

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- 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>).

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

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DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/daily_med/about.cfm. Accessed January 30, 2017.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.

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