

Pharmacy Policy Bulletin

Title: Controlled Substance Quantity Limits

Policy #: Rx.01.16

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

▸ Intent:

Controlled Substances that are subject to quantity level limits require prior authorization for quantities requested above the limit. Quantities exceeding the limit may create safety concerns or inappropriate utilization issues.

Medications subject to quantity level limits are reviewed by the Pharmacy and Therapeutics (P&T) Committee. Medications that require prior authorization per the Controlled Substances Prior Authorization must first meet prior authorization criteria before quantity limit exceptions are considered. Medication requests that constitute duplicate therapy must first meet duplicate therapy criteria before quantity limit exceptions are considered.

Controlled substances will also be subject to duplicate therapy or class quantity limits. Duplicate therapy or class quantity limits will apply within two groups of medications: long acting opioid medications and short acting opioid medications. Members who obtain a 30 day supply of any combination of long acting opioids will not be permitted to receive an additional supply of long acting opioids within that 30 day period, and members who obtain a 30 day supply of any combination of short acting opioids will not be permitted to receive an additional supply of short acting opioid medications within that 30 day period. The restriction also applies to two different strengths of the same medication.

Medications that require prior authorization per the Controlled Substances Prior Authorization must first meet prior authorization criteria before duplicate therapy exceptions are considered.

Agents that exceed quantity and/or frequency limits or duplicate therapy limits require prior authorization (i.e. clinical pharmacy and/or Medical Director review).

▸ Description:

Refer to the manufacturers' prescribing guidelines for the specific agents.

▸ Policy:

Quantity limits (INITIAL CRITERIA)

An **increased quantity of an opioid medication** is approved when **all** of the following inclusion criteria

are met:

1. Documentation of appropriate diagnosis upon visit with a qualified specialist
2. Titration to requested dose or treatment with an equal analgesic dose of another opioid
3. The requested doses do not exceed FDA or accepted clinical dosing guidelines
4. For non-cough and cold immediate release products only, BOTH of the following are met:
 - a. One of the following:
 - i. Concurrent use of a long acting agent
 - ii. Inability to tolerate long acting agent
 - b. The dose cannot be achieved with commercially available dosage forms

Quantity Limits (REAUTHORIZATION CRITERIA)

An **increased quantity of an opioid** is re-approved when **all** of the following inclusion criteria are met:

1. Documentation of appropriate diagnosis upon visit with a qualified specialist
2. Documentation to support the efficacy associated with the current regimen (e.g. pain scores, clinical response)

Authorization length: 1 year

Buprenorphine and naloxone and buprenorphine specific criteria:

INITIAL CRITERIA

Buprenorphine and naloxone (Suboxone®/Zubsolv®) and buprenorphine (Subutex®) is approved in quantities greater than 120 per 30 days when all of the following inclusion criteria are met:

1. Used concurrently with comprehensive addiction care (this includes participation in nonpharmacological interventions such as drug abuse counseling, self-help programs, behavioral therapy, or other psychosocial services)
2. Inadequate response to lower doses

REAUTHORIZATION CRITERIA

Buprenorphine and naloxone (Suboxone®/Zubsolv®) and buprenorphine (Subutex®) is re-approved in quantities greater than 120 per 30 days when all of the following inclusion criteria are met:

1. Used concurrently with comprehensive addiction care (this includes participation in nonpharmacological interventions such as drug abuse counseling, self-help programs, behavioral therapy, or other psychosocial services)
2. Documentation to support the efficacy associated with the current regimen (see Controlled Substance PA policy for medical necessity reauthorization criteria)

Authorization length: To match the existing medical necessity authorization end date (Medical necessity authorizations are issued in 6 month increments).

▸ Black Box Warning:

N/A

▸ Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Actiq® (fentanyl citrate) [prescribing information]. Salt Lake City, UT: Cephalon, Inc.; 2002. Available at: <http://www.actiq.com>. Accessed August 25, 2014.

Avinza® (morphine sulfate) [prescribing information]. San Diego, CA: Ligand Pharmaceuticals, Inc.; 2006. Available at: <http://www.avinza.com/index.aspx?text=1>. Accessed August 25, 2014.

Combunox® (oxycodone HCL/ibuprofen) [prescribing information]. St. Louis, MO: Forest Pharmaceuticals, Inc.; 2007. Available at: <http://www.combunox.com>. Accessed August 25, 2014.

Demerol (meperidine) [prescribing information]. Available online at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/005010s051lbl.pdf. 10/2011.

Endocet® (oxycodone HCL/acetaminophen) [prescribing information]. Chadds Ford, PA: Endo Pharmaceuticals, Inc.; 2007. Available at: http://www.endo.com/PDF/endocet_pack_insert_2.pdf. Accessed August 25, 2014.

Endodan® (oxycodone HCL/aspirin) [prescribing information]. Chadds Ford, PA: Endo Pharmaceuticals, Inc.; 2005. Available at: http://www.endo.com/PDF/endodan_pack_insert.pdf. Accessed August 25, 2014.

Fentora® (fentanyl buccal tablet) [prescribing information]. Fraser, PA: Cephalon, Inc.; 2007. Available at: <http://www.fentora.com>. Accessed August 25, 2014.

Kadian® (morphine sulfate). Available online at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/020616s051lbl.pdf. 04/2014.

MS Contin® (morphine sulfate) [prescribing information]. Stamford, CT: Purdue Pharma, LP; 2007. Available at: http://www.pharma.com/PI/Prescription/MS_Contin.pdf. Accessed August 25, 2014.

Opana® (oxymorphone hydrochloride) [prescribing information]. Chadds Ford, PA: Endo Pharmaceuticals, Inc.; 2006. Available at: <http://www.opana.com/>. Accessed August 25, 2014.

Oxycodone hydrochloride extended-release [package insert]. Chadds Ford, PA: Endo Pharmaceuticals, Inc.; 2004. Available at: <http://www.endo.com/>. Accessed August 25, 2014.

Oxycontin® (oxycodone HCL) [prescribing information]. Available online at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022272s022lbl.pdf. 04/2014.

Percocet® (oxycodone HCL/acetaminophen) [prescribing information]. Available online at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2006/040330s015,040341s013,040434s003lbl.pdf

Percodan® (oxycodone HCL/aspirin) [prescribing information]. Chadds Ford, PA: Endo Pharmaceuticals, Inc.; 2005. Available at: http://www.endo.com/PDF/percodan_pack_insert.pdf. Accessed August 25, 2014.


ONSOLIS(TM) buccal, soluble film, fentanyl buccal, soluble film [package insert]. Available online at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022266s009lbl.pdf. 04/2014

Facts and Comparisons website [Abstral]. Available at www.factsandcomparisons.com. Accessed August 25, 2014.

Facts and Comparisons website [Butrans]. Available at www.factsandcomparisons.com. Accessed August 25, 2014.

Facts and Comparisons website [Lazanda]. Available at www.factsandcomparisons.com. Accessed August 25, 2014.

Applicable Drugs:

 Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Drug Names	Quantity Limit per rolling 30 days, unless otherwise specified (tablet, capsule)	Maximum Daily Dose (tablet, capsule)
Acetaminophen/codeine	180	6
Acetaminophen/codeine liquid	2700ml	90ml
Aspirin/codeine	180	6
Buprenorphine patch (Butrans)	4 patches per 28 days	1 patch per 7 days
Buprenorphine (Subutex)	120	4
Buprenorphine/naloxone (Suboxone/ Zubsolv)	120	4
Butalbital/apap/caffeine/codeine (Fioricet/codeine)	180	6
Butalbital/asa/caffeine/codeine (Fiorinal/Codeine)	180	6
Codeine sulfate tablets	180	6
Codeine sulfate solution	1800ml	60ml
Fentanyl IR (Abstral, Actiq, Fentora, Onsolis Subsys)	120	4
Fentanyl nasal solution (Lazanda)	30 bottles	1 bottle
Fentanyl patch (Duragesic®)	15 patches	1 patch per 2 days
Hydrocodone bitartrate ER (Zohydro ER)	60	2
Hydrocodone/apap tabs (Vicodin, Norco, Lortab)	180	6
Hydrocodone/apap liquid (10/325/15ml, 2.5/167/5ml, 5/333/10ml, 7.5/325/15ml, 10/300/15ml)	2700ml	90ml
Hydrocodone/chlorpheniramine	450ml	15ml

Hydrocodone/chlorpheniramine/pseudoephedrine (Zutripro)	450ml	15ml
Hydrocodone/ibuprofen (Vicoprofen)	150	5
Hydromorphone (Dilaudid®)	180	6
Hydromorphone 1/1ml liquid (Dilaudid)	1500ml	50ml
Hydromorphone extended release (Exalgo)	120	4
Levorphanol tartrate	180	6
Meperidine 50mg/5ml liquid	2000ml	66ml
Meperidine HCL (Demerol, Meperitab)	180	6
Meperidine/promethazine capsules (Meprozone)	180	6
Morphine 10/5ml, 20/5ml liquid	1000ml	33ml
Morphine concentrate 20/1ml, 10/0.5ml, 5/0.25ml liquid	180ml	6ml
Morphine sulfate IR (MSIR®)	180	6
Morphine sulfate ER capsules (Avinza)	30	1
Morphine sulfate ER capsules (Kadian)	60	2
Morphine sulfate SR (MS Contin/Oramorph SR)	90	3
Oxycodone HCL (Oxy IR® / Roxicodone)	180	6
Oxycodone 5/5ml liquid	2700ml	90ml
Oxycodone 20/1ml liquid (Eth-Oxydose)	180ml	6ml
Oxycodone HCL ER (Oxycontin)	90	3
Oxycodone/acetaminophen (Endocet®/Percocet® / Primlev®)	180	6
Oxycodone/acetaminophen ER (Xartemis XR)	120	4
Oxycodone/acetaminophen 5/325/5ml liquid (Roxicet)	1000ml	33ml
Oxycodone/aspirin (Endodan®/Percodan®)	180	6
Oxycodone/ibuprofen tablets	28 per 7 days	4
Oxymorphone HCL (Opana)	180	6
Oxymorphone HCL ER (Opana ER)	90	3
Tapentadol (Nucynta)	180	6
Tapentadol ER (Nucynta ER)	60	2
Tramadol/acetaminophen (Ultracet)	40 per 5 days	8
Tramadol (Ultram)	240	8
Tramadol ER (Ultram ER/Conzip)	30	1

 Cross References:

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