

Policies Repository



Policy Title Controlled Substance Quantity Limits

Policy Number FS.CLIN.18

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 edits. 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. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. 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.

Policy	<p>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.</p> <p>Medications subject to quantity level limits are reviewed by the Pharmacy and Therapeutics (P&T) Committee.</p> <p>Medications that require prior authorization per FS.CLIN.16 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.</p> <p>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.</p> <p>Medications that require prior authorization per FS.CLIN.16 Controlled Substances Prior Authorization must first meet prior authorization criteria before duplicate therapy exceptions are considered.</p> <p>Agents that exceed quantity and/or frequency limits or duplicate therapy limits require prior authorization (ie, clinical pharmacy and/or Medical Director review).</p>
Policy Description	Refer to the manufacturers' prescribing guidelines for the specific agents.

Policy Guideline Inclusion

Authorizations will be granted for a period of one year.

Quantity limits (INITIAL CRITERIA)

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

- Documentation of appropriate diagnosis upon visit with a qualified specialist
- Documentation of titration to requested dose or treatment with an equal analgesic dose of another opioid
- The requested doses do not exceed FDA or accepted clinical dosing guidelines

Quantity Limits (REAUTHORIZATION CRITERIA)

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

- Documentation of appropriate diagnosis upon visit with a qualified specialist
- Documentation to support the efficacy associated with the current regimen (eg pain scores, clinical response)

Duplicate therapy/Class quantity limits (INITIAL REQUESTS)

Duplicate opioid requests are approved when **all** of the following inclusion criteria are met:

- Documentation of appropriate diagnosis upon visit with a qualified specialist
- Documentation of insufficient response to previous treatments
- Documentation of need for more than one long acting or more than one short acting concomitant medication that exceeds a 30 day supply
- The requested doses do not exceed FDA or accepted clinical dosing guidelines
- In addition one of the following criteria must be met
 - Documentation of intolerance or contraindication to higher doses of a single opioid
 - Dose requested does not exist in single tablet form

Duplicate therapy/Class quantity limits (REAUTHORIZATION REQUESTS)

Duplicate opioid requests are re-approved when **all** of the following inclusion criteria are met:

- Documentation of appropriate diagnosis upon visit with a qualified specialist
- Documentation to support the efficacy associated with the current regimen (eg pain scores, clinical response)

Policy Guideline Exclusion

Quantity Limits (INITIAL CRITERIA)

An **increased quantity of an opioid medication** is denied when **any** of the following exclusion criteria are present:

- No documentation of appropriate diagnosis upon visit with a qualified specialist
- No documentation of titration to requested dose or treatment with an equal analgesic dose of

- another opioid
- The requested doses exceed FDA or accepted clinical dosing guidelines

Quantity limits (REAUTHORIZATION CRITERIA)

An **increased quantity of an opioid medication** is denied when **any** of the following exclusion criteria are present:

- No documentation of appropriate diagnosis upon visit with a qualified specialist
- No documentation to support the efficacy associated with the current regimen (eg pain scores, clinical response)

Duplicate therapy/Class quantity limits (INITIAL REQUESTS)

Duplicate opioid requests are denied when **any** of the following exclusion criteria are present:

- No documentation of appropriate diagnosis upon visit with a qualified specialist
- No documentation of insufficient response to previous treatments
- No documentation of need for more than one long acting or more than one short acting concomitant medication that exceeds a 30 day supply
- The requested doses exceed FDA or accepted clinical dosing guidelines
- No documentation of both of the following
 - Intolerance or contraindication to higher doses of a single opioid
 - Dose requested does not exist in single tablet form

Duplicate therapy/Class quantity limits (REAUTHORIZATION REQUESTS)

Duplicate opioid requests are denied when **any** of the following exclusion criteria are present:

- No documentation of appropriate diagnosis upon visit with a qualified specialist
- No documentation to support the efficacy associated with current regimen (eg pain scores, clinical response)

Policy List of Applicable Drugs

Agent Names	Number of Units per Month (unless another period of time is noted)
Acetaminophen/codeine	180 units per month
Acetaminophen/codeine liquid	2700ml per month
Actiq (fentanyl citrate)	120 units per month
Aspirin/codeine	180 units per month
Avinza® (morphine sulfate)	30 units per month
Butalbital/aspirin/caffeine 50/325/40	180 units per month
Codeine/butalbital/acetaminophen/caffeine 30-50-325	180 units per month
codeine/butalbital/asa/caffeine 30-50-325	180 units per month
Codeine phosphate	180 units per month
Codeine sulfate	180 units per month
Combunox® (oxycodone HCL/ibuprofen)	28 tablets per 7 days

Darvon N 100	180 units per month
Demerol® (meperidine HCL)	180 units per month
Dilaudid (hydromorphone) 1/1ml liquid	1500ml per month
Dilaudid® (hydromorphone HCL)	180 units per month
Duragesic® (fentanyl patches)	15 patches per month
Endocet®/Percocet®/Tylox®/Magnacet™ (oxycodone/acetaminophen)	180 units per month
Endodan®/Percodan® (aspirin/oxycodone)	180 units per month
Fentora (fentanyl citrate)	120 units per month
Hydrocodone/apap tabs 7.5/750 and 10/750	150 units per month
Hydrocodone/apap tabs (acetaminophen less than 750mg)	180 units per month
Hydrocodone/apap 7.5/500/15ml liquid	2700ml per month
Hycet (hydrocodone/apap) 7.5/325/15ml liquid	2700ml per month
Hydrocodone/apap 10/500/15ml liquid	2700ml per month
Hydrocodone/apap 10/325/15ml liquid	2700ml per month
Hydrocodone/apap 2.5/167/5ml liquid	2700ml per month
Hydrocodone/apap 5/333/10ml liquid	2700ml per month
Hydrocodone/ibuprofen	150 units per month
Kadian® (morphine sulfate)	60 units per month
Levorphanol tartrate	180 units per month
MSIR® (morphine sulfate)	180 units per month
MS Contin® (morphine sulfate)	90 units per month
Meperidine 50mg/5ml liquid	2000ml per month
Meperidine HCL/acetaminophen	180 units per month
Meperidine HCL/promethazine	180 units per month
Meperitab® (meperidine HCL)	180 units per month
Meprozone (meperidine HCL/promethazine HCL)	180 units per month
Morphine 10/5ml liquid	1000ml per month
Morphine 20/5ml liquid	1000ml per month
Morphine 20/1ml, 10/0.5ml, 5/0.25ml liquid	180ml per month
Morphine sulfate	180 units per month
Morphine sulfate SR	90 units per month
Nucynta (tapentadol)	180 units per month
Opana (oxymorphone HCL)	180 units per month
Opana ER (oxymorphone HCL ER)	90 units per month
Oramorph SR® (morphine sulfate SR)	90 units per month

Oxy IR® / Roxycodone (oxycodone HCL)	180 units per month
Oxycodone 5/5ml liquid	2700ml per month
Oxycodone 20/1ml liquid	180ml per month
Eth-Oxydose 20/1ml liquid	180ml per month
Oxycontin® (oxycodone HCL ER)	90 units per month
Propoxyphene 65mg	180 units per month
Propoxyphene/apap	180 units per month
Roxicet 5/325/5ml liquid	1000ml per month

Long Acting

Drug Name
Morphine sulfate SR / Ms contin / Oramorph SR
Oxycontin / oxycodone hcl SR
Opana ER
Avinza
Fentanyl/ Duragesic
Kadian

Short Acting

Drug Name
Fentanyl citrate/actiq
Fentora
Hydromorphone hcl / dilaudid
Demerol/ meperidine hcl
Meperidine containing products
Codeine
Acetaminophen/codeine
Hydrocodone containing pain products

Oxycodone IR containing products
Morphine IR containing products
Propoxyphene containing products
Opana / oxymorphone
Levorphanol tartrate
Nucynta/tapentadol

Dosing and Administration

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

Policy References

Actiq® (fentanyl citrate) [prescribing information]. Salt Lake City, UT: Cephalon, Inc.; 2002. Available at: <http://www.actiq.com>. Accessed July 28, 2009.

Avinza® (morphine sulfate) [prescribing information]. San Diego, CA: Ligand Pharmaceuticals, Inc.; 2006. Available at: <http://www.avinza.com/index.aspx?text=1>. Accessed July 28, 2009.

Combunox® (oxycodone HCL/ibuprofen) [prescribing information]. St. Louis, MO: Forest Pharmaceuticals, Inc.; 2007. Available at: <http://www.combunox.com>. Accessed July 28, 2009.

Demerol (meperidine) [prescribing information]. Bridgewater, NJ: Sanofi-aventis; 2005.

Dilaudid® (hydromorphone HCL). *USP DI Drug Information for the Health Care Professional 2003* [book on CD-ROM]. Jackson WY: Teton Data Systems; 2003. Based on *USP DI Drug Information for the Health Care Professional*. 23rd ed. Greenwood Village, CO: Thompson MICROMEDEX; 2003. STAT!-Ref Medical Reference Library.

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 July 28, 2009.

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 July 28, 2009.

Fentora® (fentanyl buccal tablet) [prescribing information]. Fraser, PA: Cephalon, Inc.; 2007. Available at: <http://www.fentora.com>. Accessed July 28, 2009.

Kadian® (morphine sulfate). *USP DI Drug Information for the Health Care Professional 2003* [book on CD-ROM]. Jackson WY: Teton Data Systems; 2003. Based on *USP DI Drug Information for the Health Care Professional*. 23rd ed. Greenwood Village, CO: Thompson MICROMEDEX; 2003. STAT!-Ref Medical Reference Library.

Levorphanol tartrate [prescribing information]. Columbus, OH: Roxane Laboratories, Inc.; 2008.

Meperitab® (meperidine HCL). *USP DI Drug Information for the Health Care Professional 2003* [book on CD-ROM]. Jackson WY: Teton Data Systems; 2003. Based on *USP DI Drug Information for the Health Care Professional*. 23rd ed. Greenwood Village, CO: Thompson MICROMEDEX; 2003. STAT!-Ref Medical Reference Library.

Meprozone® (meperidine HCL/promethazine HCL). *USP DI Drug Information for the Health Care Professional 2003* [book on CD-ROM]. Jackson WY: Teton Data Systems; 2003. Based on *USP DI Drug Information for the Health Care Professional*. 23rd ed. Greenwood Village, CO: Thompson MICROMEDEX; 2003. STAT!-Ref Medical Reference Library.

MS Contin® (morphine sulfate) [prescribing information]. Stamford, CT: Purdue Pharma, LP; 2007. Available at: http://www.pharma.com/PI/Prescription/MS_Contin.pdf. Accessed July 28, 2009.

MSIR® (morphine sulfate) [prescribing information]. Stamford, CT: Purdue Pharma, LP; 2004. Available at: <http://www.pharma.com/PI/Prescription/MSIR.pdf>. Accessed July 28, 2009.

Opana® (oxymorphone hydrochloride) [prescribing information]. Chadds Ford, PA: Endo Pharmaceuticals, Inc.; 2006. Available at: <http://www.opana.com/>. Accessed July 28, 2009.

Opana ER® (oxymorphone hydrochloride extended release) [prescribing information]. Chadds Ford, PA: Endo Pharmaceuticals, Inc.; 2008. Available at: <http://www.opana.com/>. Accessed July 28, 2009.

Oramorph (morphine sulfate) [prescribing information]. Columbus, OH: Roxane Laboratories; 2001.

Oramorph SR® (morphine sulfate). *USP DI Drug Information for the Health Care Professional 2003* [book on CD-ROM]. Jackson WY: Teton Data Systems; 2003. Based on *USP DI Drug Information for the Health Care Professional*. 23rd ed. Greenwood Village, CO: Thompson MICROMEDEX; 2003. STAT!-Ref Medical Reference Library.

Oxy IR® (oxycodone HCL) [prescribing information]. Stamford, CT: Purdue Pharma, LP; 2007. Available at: <http://www.pharma.com/PI/Prescription/OxyIR.pdf>. Accessed July 28, 2009.

Oxycodone hydrochloride extended-release [package insert]. Chadds Ford, PA: Endo Pharmaceuticals, Inc.; 2004. Available at: <http://www.endo.com/>. Accessed July 28, 2009.

Oxycontin® (oxycodone HCL) [prescribing information]. Stamford, CT: Purdue Pharma, LP; 2007. Available at: <http://www.pharma.com/PI/Prescription/Oxycontin.pdf>. Accessed July 28, 2009.

Percocet® (oxycodone HCL/acetaminophen) [prescribing information]. Chadds Ford, PA: Endo Pharmaceuticals, Inc.; 2006. Available at: http://www.endo.com/PDF/percocet_pack_insert_2.pdf. Accessed July 28, 2009.

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 July 28, 2009.

Roxicet® (oxycodone HCL/acetaminophen). *USP DI Drug Information for the Health Care Professional 2003* [book on CD-ROM]. Jackson WY: Teton Data Systems; 2003. Based on *USP DI Drug Information for the Health Care Professional*. 23rd ed. Greenwood Village, CO: Thompson MICROMEDEX; 2003. STAT!-Ref Medical Reference Library.

Roxicodone® (oxycodone HCL). *USP DI Drug Information for the Health Care Professional 2003* [book on CD-ROM]. Jackson WY: Teton Data Systems; 2003. Based on *USP DI Drug Information for the Health Care Professional*. 23rd ed. Greenwood Village, CO: Thompson MICROMEDEX; 2003. STAT!-Ref Medical Reference Library.

Tylox® (oxycodone HCL/acetaminophen) [prescribing information]. Spring House, PA: Ortho-McNeil Pharmaceutical; 2000. Available at: <http://www.orthomcneil.com>. Accessed July 28, 2009.

Policy Link to Related Policies

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