Drug Use Evaluation: Short Acting Opioids (SAO)

Summary

- Short acting opioid analgesics are one of the most prescribed (top 10) and highest cost (top 20) medication classes for the Oregon Fee For Service (FFS) Medicaid program
- A minority of members without medical claims for cancer treatment are receiving short acting opioids exceeding daily doses recommended by current evidence based guidelines
- Of these members, a significant proportion have medical claims suggesting increased risk of developing misuse or abuse of these medications

Recommendations

- Apply the same prior authorization criteria to both short and long acting opioids. Applying these criteria will:
    - Minimize the use of opioid analgesics at doses exceeding current guidelines
    - Increased surveillance for misuse/abuse
    - Provide prescriber education regarding the risks of high dose opioids
- Monitor the effects of the new PA criteria on:
    - Proportion of members on high vs. low dose SAO
    - Proportion of members using SAO vs. LAO
    - Members with dose escalations exceeding recommended doses
- Monitor the impact on workload on FFS Medicaid Pharmacy Benefits Management vendor:
    - Track the number of PA requested for high dose SAO
    - Track the number of PA appeals for denied requests for high dose SAO

Drug Use Evaluation: Short Acting Opioids (SAO)

Background

As discussed in detail in the DURM Long Acting Opioid (LAO) Drug Use Evaluation (DUE), the off label use of opioids has increased significantly in the general US population as well as the Oregon Medicaid Program.[1] Studies evaluating mortality rates have conflicting results with some studies showing increased mortality associated with increasing prescriptions of opioids.[2] Chronic opioid use has been associated with effects on hormone levels, abuse and addiction, tolerance and hyperalgesia.[3] Mental health diagnoses and a history of substance abuse have been associated with a greater risk of increase utilization and opioid abuse. [4,5] The treatment of chronic pain with opioids has been shown to have little effect on functional status. [6]

Concerns over misuse and abuse have garnered national and regional attention. In 2011 the Executive Office of the President stated: "Prescription drug misuse and abuse is a major public health and public safety crisis."[7] The Director of the Center for Disease Control (CDC) described misuse and abuse of prescriptions as an "epidemic."[8] The Centers for Medicare and Medicaid Services (CMS) in 2011 indicated that Prior Authorizations are a part of a "robust state controlled prescription drug program."[9] Washington State enacted House Bill 2876 mandating pain specialist consultations for patients exceeding 120 morphine equivalents daily (MED). Multnomah county currently restricts patients to 180 MED, with plans to further reduce to 60 MED in 2012.

Opioid analgesic use accounts for significant expenditures in Oregon Medicaid Fee For Service (FFS) and is the fifth highest cost medication class.[10] Generic oxycodone alone is the third most frequently prescribed medication.[11]

Drug Use Evaluation

In response to safety concerns, Oregon FFS Medicaid performed a Drug Use Evaluation (DUE) for SAO analgesics. This DUE sought to determine if SAO are used in high risk patients at doses exceeding those recommended by current guidelines. Additionally, we sought to determine the potential benefits of applying current LAO PA criteria to SAO.

Methods

Selection criteria included all FFS pharmacy prescription claims for SAO from January 1, 2009 thru November 30, 2011. SAO are defined as medications in standard therapeutic class 40 with formulations dosed more than twice daily which are not in extended release formulations or transdermal patches. Diagnoses were determined based on medical claims data starting 6 months before the study period through the end of the study period (i.e. July 1, 2008 - November 30, 2011). Cancer was identified from ICD-9 codes 140.0-239.9 and 338.3. Mental Health disorders were identified by ICD-9 codes 293-302.9 and 306-331.6. Fibromyalgia was identified by ICD-9 729.1. Substance abuse was identified by ICD-9 codes 303-305 (excluding 305.1), 291, 292, V46, and V681. Costs and utilization trends are reported as

member per month (PMPM) values. Prescription costs include only the amount paid by the FFS program; third party payments are not included.

Several short acting opioids were excluded from our analysis. Parenteral formulations were excluded from analysis. Tramadol and propoxyphene were excluded due to low abuse potential. Sublingual buprenorphine/naltrexone (Suboxone®) is not approved for the treatment of chronic pain and was also excluded. Pentazocine was excluded due to lack of a reliable conversion factor. Butorphanol and opium were excluded as they have particular uses and are not used for the general management of pain. Tapentadol (Nucynta®) was excluded, because the package insert specifies a maximum daily dose.[12] Prescriptions for a supply of less than five days can skew dose calculations and therefore these claims have been excluded from analysis involving dose levels.

High dose (HD) opioids are defined as total dose exceeding 120 MED. Acceptable doses (AD) are defined as dosages less than or equal to 120 MED. Morphine dose equivalents were calculated by converting each opioid into morphine equivalents per dispensable unit. The number of units prescribed per day was multiplied by the morphine equivalent per dispensable unit to determine the MED. A complete table of opioid formulations encountered and the corresponding MED results are included in Appendix A.

Members receiving chronic SAO therapy were identified as a subgroup of interest. Chronic therapy is defined as at least three calendar months of opioid therapy during the study period with the quantity supplied for all prescriptions totaling at least half the number of calendar days of therapy. This is intended to include patients who take less than the prescribed quantity continuously and patients who have temporarily stopped what would be considered chronic therapy.

Results

Figure 1 demonstrates the total opioid utilization, with SAO compromising 72-78% of all prescriptions. Total PMPM prescriptions declined during the study period, but the proportion of SAO to LAO was not significantly affected.

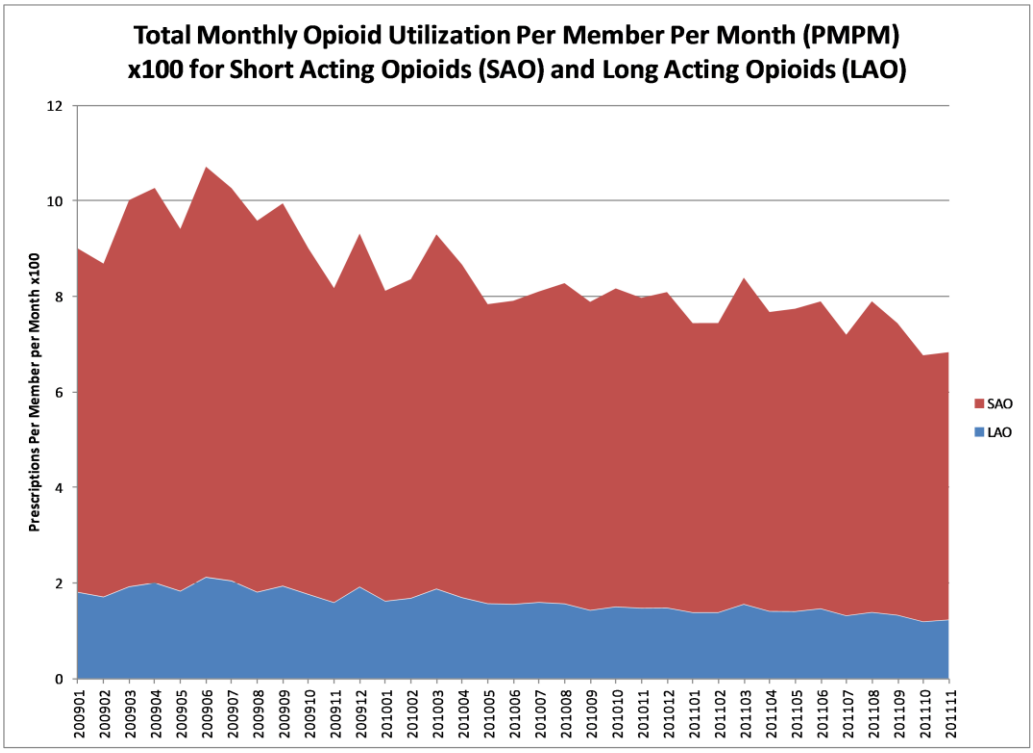


Figure 1. Trend of opioid utilization and proportion of SAO vs. LAO

Figure 2 compares SAO volume and cost PMPM. January 2011 shows a significant drop in cost PMPM. This timing is consistent with a change in pharmacy reimbursement rules for FFS member claims and the implementation of the SAO preferred drug list (PDL).

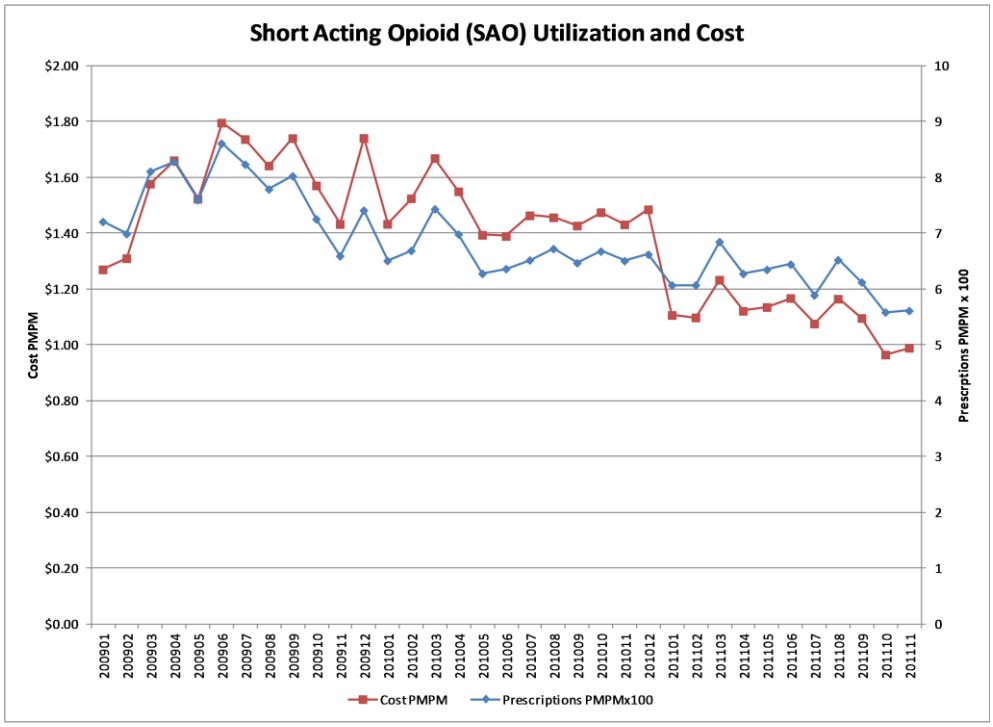


Figure 2. Trend in Utilization volume and costs for SAO

Figure 3 illustrates the average MED (lines) for HD and AD as well as the total volume of prescriptions (bars). The average MED for AD members was relatively stable, varying from 38-41 MED (approximately eight Vicodin® daily). The average dose for HD patients varied from 217 – 263 MED.

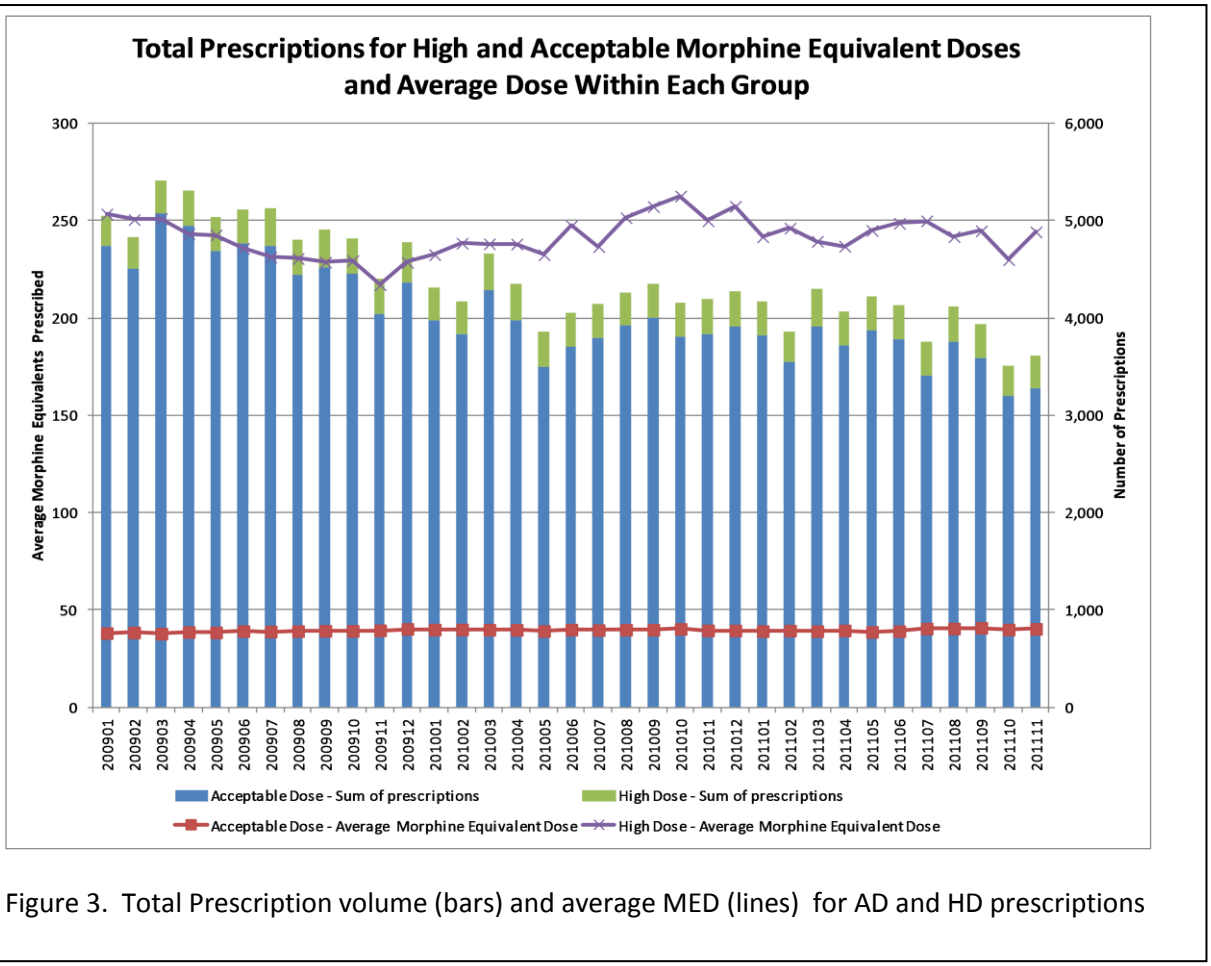


Figure 3. Total Prescription volume (bars) and average MED (lines) for AD and HD prescriptions

Of all patients receiving HD SAO, 47% have had at least one cancer-related medical claim (Figure 4, Table 1). Figures 5 and 6 show members without cancer claims receiving HD SAO who have claims suggesting an increased risk of developing substance abuse/misuse. Fifteen percent of patients with dose escalations of at least 50% have a final dose exceeding 120 MED (figure 7). Finally figure 8 demonstrates for all non-cancer patients receiving chronic SAO therapy, the proportion of HD vs. AD remains essentially unchanged during the study period (~95% AD, ~5% HD).

Category	Members	Prescriptions	Total Paid ($)	Average MED
Overall	1,753	29,391	1,614,229	243
Cancer	824	13,874	789,916	258
Non-Cancer	929	15,517	824,313	230

Table 1. Members receiving at least one SAO prescription exceeding 120 MED with and without cancer-associated medical claims

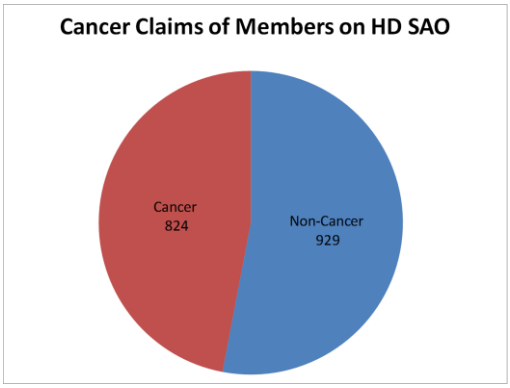


Figure 4 HD SAO use in cancer and non-cancer patients

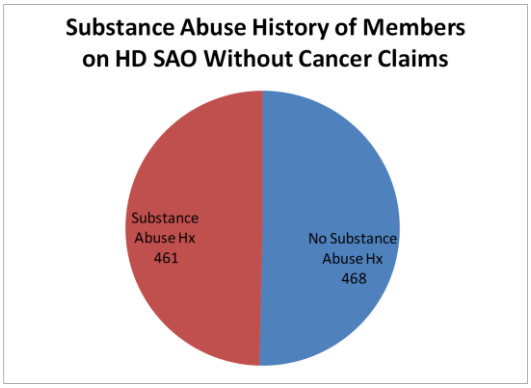


Figure 5 HD SAO use in non-cancer patients with a history of substance abuse

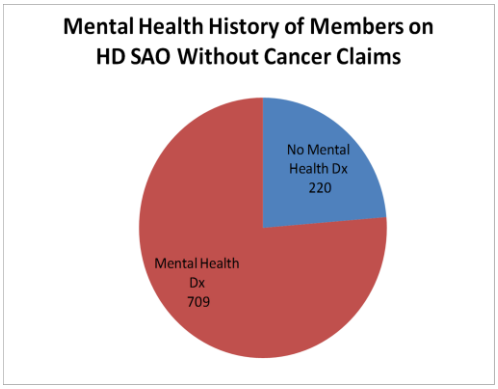


Figure 6 HD SAO use in non-cancer patients with a history of mental health disorders

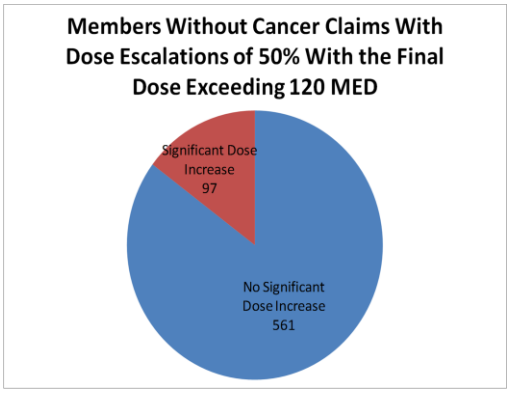


Figure 7 Dose escalations to high dose levels

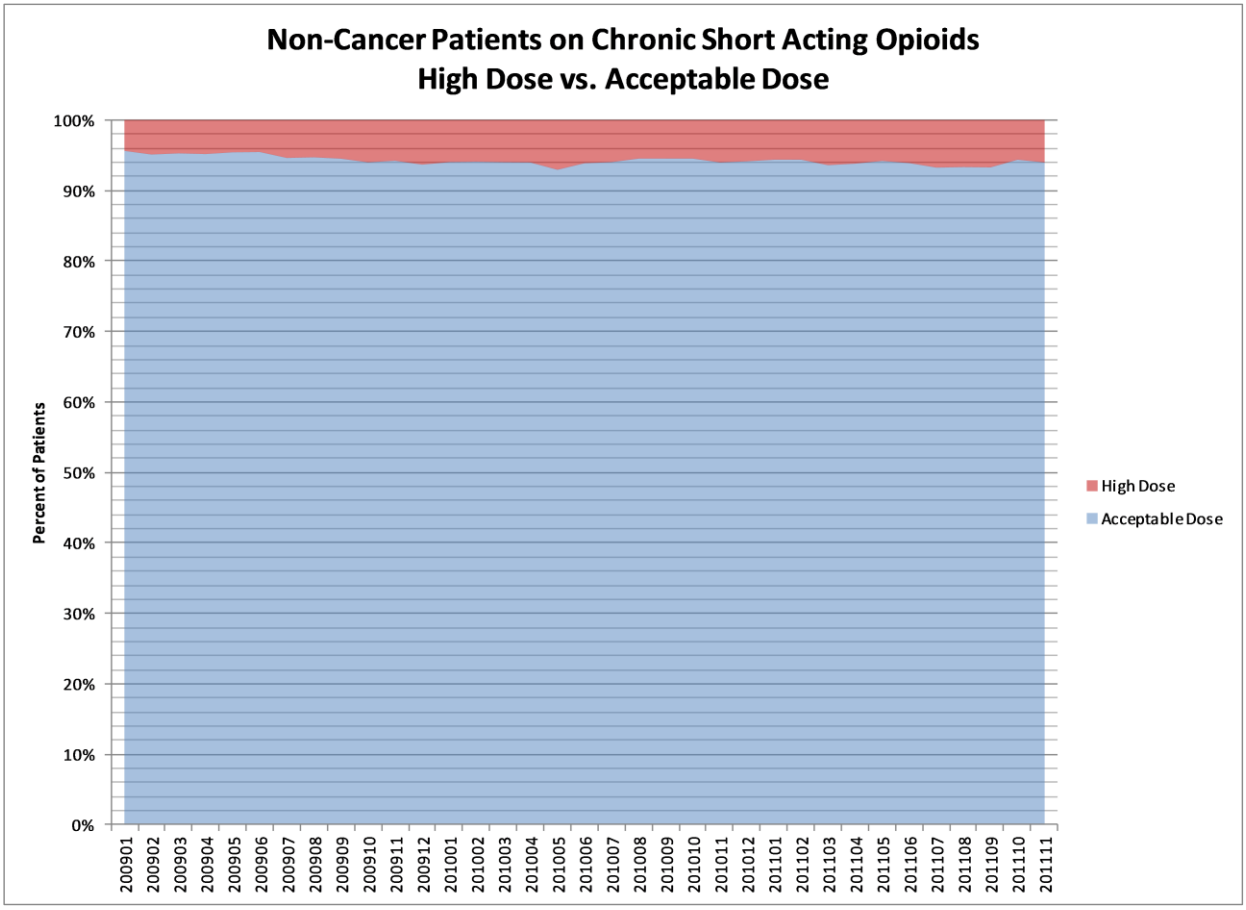


Figure 8. Proportion of non-cancer chronic SAO patients on high and acceptable dosages

Discussion

Over half of the members receiving HD SAO do not have claims indicating a diagnosis of cancer. Of these patients, 76% have a mental health diagnosis which has been identified as a risk factor for future or current substance abuse and drug seeking behaviors.[13] Patients with a recent history of substance abuse compose 50% of the members on HD SAO who do not have claims indicating cancer. These data suggest that many of these members may be at elevated risk of developing substance abuse and misuse behaviors.

The risk factors of overuse and misuse found in the LAO DUE are also found in patients receiving SAO therapy.1 Most members (~95%) using SAO are treated at dosages consistent with current pain treatment guidelines (i.e. acceptable dosage group). Yet there are a significant number of patients receiving HD SAO who have a history of substance abuse or risk factors for substance abuse or misuse. The LAO DUE recommended changes to the Prior Authorization to restrict use to address these concerns (See Appendix B). Applying these same criteria should decrease use of HD SAO in non-cancer patients, as well as improve monitoring in patients with risk factors for misuse and abuse through the Pharmacy Management Program (a.k.a. Lock-In Program).

Attention to patient care and adequate pain control is essential for the success of this program. Approximately 5% of patients receiving SAO therapy would qualify for evaluation of PA criteria (i.e. exceeding 120MED for non-cancer pain). According to the proposed LAO criteria, patients already being treated for above the line pain diagnoses receiving opioids from one provider and one pharmacy would generally be approved for 6 month extensions after the prescriber acknowledges the risks associated with high dose opioids. This will protect 95% of SAO users for burdensome and unnecessary prior authorization requests, while providing additional safety controls for the minority of members at elevated risk of abuse and misuse.

Limitations

Analysis of claims data has many limitations. Diagnosis data may be incomplete, inaccurate, or untimely. Medical claims typically appear in 6 months, but a minority of claims may not be submitted for over one year. Our data analysis is limited to FFS Medicaid members and associated claims. Managed Care Organization (MCO) medical claims data was included, but not prescription data. Members of Oregon Medicaid change from FFS to MCO plans regularly. Such switches could cause members chronic treated for pain appear as intermittently treated. Any prescriptions which were purchased for cash or paid for by other third party payers would not appear in our analysis. The Oregon Medicaid Program is not currently allowed access to the Oregon Prescription Drug Monitoring Program (PDMP) database, without which cash claims cannot be assessed.

Recommendations

- Apply the same prior authorization criteria to both short and long acting opioids (Appendix B). Applying these criteria will:
    - Manage the use of opioid analgesics at doses exceeding 120MED
    - Increased surveillance for misuse/abuse
    - Provide prescriber education regarding the risks of high dose opioids
- Monitor the effects of the new PA criteria on:
    - Proportion of members on high vs. low dose SAO
    - Proportion of members using SAO vs. LAO
    - Members with dose escalations exceeding 120 MED
    - Members with dose reduction from above 120 MED to below 120MED
- Monitor the impact on workload on FFS Medicaid Pharmacy Benefits Management vendor:
    - Track the number of PA requested for high dose SAO
    - Track the number of PA appeals for denied requests for high dose SAO

Appendix A – Morphine Equivalents

Generic	Formulation Strength	Form	Unit Type	Opioid Per Unit	Conversion Factor	Morphine Equivalent Per Unit
ACETAMINOPHEN WITH CODEINE	120 mg-12 mg/5 mL	ELIXIR	ML	2.4	0.15	0.36
ACETAMINOPHEN WITH CODEINE	120 mg-12 mg/5 mL	ORAL SUSP	ML	2.4	0.15	0.36
ACETAMINOPHEN WITH CODEINE	300 mg-15 mg	TABLET	EA	15	0.15	2.25
ACETAMINOPHEN WITH CODEINE	300 mg-30 mg	TABLET	EA	30	0.15	4.5
ACETAMINOPHEN WITH CODEINE	300 mg-60 mg	TABLET	EA	60	0.15	9
ASPIRIN/CODEINE PHOSPHATE	325 mg-30 mg	TABLET	EA	30	0.15	4.5
CODEINE PHOS/CARISOPRODOL/ASA	16 mg-200 mg-325 mg	TABLET	EA	16	0.15	2.4
CODEINE SULF	15 mg	TABLET	EA	15	0.15	2.25
CODEINE SULF	30 mg	TABLET	EA	30	0.15	4.5
CODEINE SULF	60 mg	TABLET	EA	60	0.15	9
CODEINE/BUTALBIT/ACETAMIN/CAFF	30 mg-50 mg-325 mg-40 mg	CAPSULE	EA	30	0.15	4.5
CODEINE/BUTALBITAL/ASA/CAFFEIN	30 mg-50 mg-325 mg-40 mg	CAPSULE	EA	30	0.15	4.5
FENTANYL	12 mcg/hour	PATCH TD72	PER DAY	12	4.00	48
FENTANYL	25 mcg/hour	PATCH TD72	PER DAY	25	4.00	100
FENTANYL	50 mcg/hour	PATCH TD72	PER DAY	50	4.00	200
FENTANYL	75 mcg/hour	PATCH TD72	PER DAY	75	4.00	300
FENTANYL CITRATE	200 mcg	LOZENGE HD	EA	200	0.03	6
FENTANYL CITRATE	400 mcg	LOZENGE HD	EA	400	0.03	12
FENTANYL CITRATE	1,200 mcg	LOZENGE HD	EA	1200	0.03	36
FENTANYL CITRATE	1,600 mcg	LOZENGE HD	EA	1600	0.03	48
FENTANYL CITRATE	100 mcg	TABLET EFF	EA	100	0.12	12
FENTANYL CITRATE	200 mcg	TABLET EFF	EA	200	0.12	24
HYDROCODONE BIT/ACETAMINOPHEN	7.5 mg-325 mg/15 mL	SOLUTION	ML	0.5	1.00	0.5
HYDROCODONE BIT/ACETAMINOPHEN	7.5 mg-500 mg/15 mL	SOLUTION	ML	0.5	1.00	0.5
HYDROCODONE BIT/ACETAMINOPHEN	7.5 mg-500 mg/15 mL (15 mL)	SOLUTION	ML	0.5	1.00	0.5
HYDROCODONE BIT/ACETAMINOPHEN	2.5 mg-500 mg	TABLET	EA	2.5	1.00	2.5
HYDROCODONE BIT/ACETAMINOPHEN	5 mg-325 mg	TABLET	EA	5	1.00	5
HYDROCODONE BIT/ACETAMINOPHEN	5 mg-500 mg	TABLET	EA	5	1.00	5
HYDROCODONE BIT/ACETAMINOPHEN	7.5 mg-325 mg	TABLET	EA	7.5	1.00	7.5
HYDROCODONE BIT/ACETAMINOPHEN	7.5 mg-500 mg	TABLET	EA	7.5	1.00	7.5
HYDROCODONE BIT/ACETAMINOPHEN	7.5 mg-650 mg	TABLET	EA	7.5	1.00	7.5
HYDROCODONE BIT/ACETAMINOPHEN	7.5 mg-750 mg	TABLET	EA	7.5	1.00	7.5
HYDROCODONE BIT/ACETAMINOPHEN	10 mg-325 mg	TABLET	EA	10	1.00	10
HYDROCODONE BIT/ACETAMINOPHEN	10 mg-400 mg	TABLET	EA	10	1.00	10
HYDROCODONE BIT/ACETAMINOPHEN	10 mg-500 mg	TABLET	EA	10	1.00	10
HYDROCODONE BIT/ACETAMINOPHEN	10 mg-650 mg	TABLET	EA	10	1.00	10
HYDROCODONE BIT/ACETAMINOPHEN	10 mg-660 mg	TABLET	EA	10	1.00	10
HYDROCODONE BIT/ACETAMINOPHEN	10 mg-750 mg	TABLET	EA	10	1.00	10
HYDROCODONE/IBUPROFEN	7.5 mg-200 mg	TABLET	EA	7.5	1.00	7.5
HYDROCODONE/IBUPROFEN	10 mg-200 mg	TABLET	EA	10	1.00	10
HYDROMORPHONE HCL	1 mg/mL	LIQUID	ML	1	4.00	4
HYDROMORPHONE HCL	3 mg	SUPP.RECT	EA	3	4.00	12
HYDROMORPHONE HCL	8 mg	TAB ER 24	EA	8	4.00	32
HYDROMORPHONE HCL	12 mg	TAB ER 24	EA	12	4.00	48
HYDROMORPHONE HCL	16 mg	TAB ER 24	EA	16	4.00	64
HYDROMORPHONE HCL	2 mg	TABLET	EA	2	4.00	8
HYDROMORPHONE HCL	4 mg	TABLET	EA	4	4.00	16
HYDROMORPHONE HCL	8 mg	TABLET	EA	8	4.00	32
IBUPROFEN/OXYCODONE HCL	400 mg-5 mg	TABLET	EA	5	1.50	7.5
LEVORPHANOL TARTRATE	2 mg	TABLET	EA	2	30.00	60
MEPERIDINE HCL	50 mg	TABLET	EA	50	0.10	5
MEPERIDINE HCL	100 mg	TABLET	EA	100	0.10	10
METHADONE HCL	10 mg/mL	ORAL CONC	ML	10	3.75	37.5
METHADONE HCL	5 mg/5 mL	SOLUTION	ML	1	3.75	3.75
METHADONE HCL	10 mg/5 mL	SOLUTION	ML	2	3.75	7.5
METHADONE HCL	5 mg	TABLET	EA	5	3.75	18.75
METHADONE HCL	10 mg	TABLET	EA	10	3.75	37.5
METHADONE HCL	40 mg	TABLET SOL	EA	40	3.75	150
MORPHINE SULFATE	10 mg	CAP ER PEL	EA	10	1.00	10
MORPHINE SULFATE	20 mg	CAP ER PEL	EA	20	1.00	20

Generic	Formulation Strength	Form	Unit Type	Opioid Per Unit	Conversion Factor	Morphine Equivalent Per Unit
MORPHINE SULFATE	30 mg	CAP ER PEL	EA	30	1.00	30
MORPHINE SULFATE	50 mg	CAP ER PEL	EA	50	1.00	50
MORPHINE SULFATE	60 mg	CAP ER PEL	EA	60	1.00	60
MORPHINE SULFATE	80 mg	CAP ER PEL	EA	80	1.00	80
MORPHINE SULFATE	100 mg	CAP ER PEL	EA	100	1.00	100
MORPHINE SULFATE	30 mg	CPMP 24HR	EA	30	1.00	30
MORPHINE SULFATE	60 mg	CPMP 24HR	EA	60	1.00	60
MORPHINE SULFATE	75 mg	CPMP 24HR	EA	75	1.00	75
MORPHINE SULFATE	90 mg	CPMP 24HR	EA	90	1.00	90
MORPHINE SULFATE	120 mg	CPMP 24HR	EA	120	1.00	120
MORPHINE SULFATE	10 mg/5 mL	SOLUTION	ML	2	1.00	2
MORPHINE SULFATE	20 mg/5 mL	SOLUTION	ML	4	1.00	4
MORPHINE SULFATE	100 mg/5 mL (20 mg/mL)	SOLUTION	ML	20	1.00	20
MORPHINE SULFATE	5 mg	SUPP.RECT	EA	5	1.00	5
MORPHINE SULFATE	10 mg	SUPP.RECT	EA	10	1.00	10
MORPHINE SULFATE	20 mg	SUPP.RECT	EA	20	1.00	20
MORPHINE SULFATE	15 mg	TABLET	EA	15	1.00	15
MORPHINE SULFATE	30 mg	TABLET	EA	30	1.00	30
MORPHINE SULFATE	15 mg	TABLET ER	EA	15	1.00	15
MORPHINE SULFATE	30 mg	TABLET ER	EA	30	1.00	30
MORPHINE SULFATE	60 mg	TABLET ER	EA	60	1.00	60
MORPHINE SULFATE	100 mg	TABLET ER	EA	100	1.00	100
MORPHINE SULFATE	200 mg	TABLET ER	EA	200	1.00	200
MORPHINE SULFATE/NALTREXONE	20 mg-0.8 mg	CAP ER PEL	EA	20	1.00	20
MORPHINE SULFATE/NALTREXONE	100 mg-4 mg	CAP ER PEL	EA	100	1.00	100
OXYCODONE HCL	5 mg	CAPSULE	EA	5	1.50	7.5
OXYCODONE HCL	20 mg/mL	ORAL CONC	ML	20	1.50	30
OXYCODONE HCL	20 mg/mL (1 mL)	ORAL CONC	ML	20	1.50	30
OXYCODONE HCL	5 mg/5 mL	SOLUTION	ML	1	1.50	1.5
OXYCODONE HCL	10 mg	TAB ER 12H	EA	10	1.50	15
OXYCODONE HCL	15 mg	TAB ER 12H	EA	15	1.50	22.5
OXYCODONE HCL	20 mg	TAB ER 12H	EA	20	1.50	30
OXYCODONE HCL	30 mg	TAB ER 12H	EA	30	1.50	45
OXYCODONE HCL	40 mg	TAB ER 12H	EA	40	1.50	60
OXYCODONE HCL	60 mg	TAB ER 12H	EA	60	1.50	90
OXYCODONE HCL	80 mg	TAB ER 12H	EA	80	1.50	120
OXYCODONE HCL	5 mg	TABLET	EA	5	1.50	7.5
OXYCODONE HCL	10 mg	TABLET	EA	10	1.50	15
OXYCODONE HCL	15 mg	TABLET	EA	15	1.50	22.5
OXYCODONE HCL	20 mg	TABLET	EA	20	1.50	30
OXYCODONE HCL	30 mg	TABLET	EA	30	1.50	45
OXYCODONE HCL/ACETAMINOPHEN	5 mg-500 mg	CAPSULE	EA	5	1.50	7.5
OXYCODONE HCL/ACETAMINOPHEN	5 mg-325 mg/5 mL	SOLUTION	ML	1	1.50	1.5
OXYCODONE HCL/ACETAMINOPHEN	2.5 mg-325 mg	TABLET	EA	2.5	1.50	3.75
OXYCODONE HCL/ACETAMINOPHEN	5 mg-325 mg	TABLET	EA	5	1.50	7.5
OXYCODONE HCL/ACETAMINOPHEN	5 mg-500 mg	TABLET	EA	5	1.50	7.5
OXYCODONE HCL/ACETAMINOPHEN	7.5 mg-325 mg	TABLET	EA	7.5	1.50	11.25
OXYCODONE HCL/ACETAMINOPHEN	7.5 mg-500 mg	TABLET	EA	7.5	1.50	11.25
OXYCODONE HCL/ACETAMINOPHEN	10 mg-325 mg	TABLET	EA	10	1.50	15
OXYCODONE HCL/ACETAMINOPHEN	10 mg-650 mg	TABLET	EA	10	1.50	15
OXYCODONE HCL/ASPIRIN	4.8355 mg-325 mg	TABLET	EA	4.8355	1.50	7.25325
OXYCODONE HCL/OXYCODON TER/ASA	4.5 mg-0.38 mg-325 mg	TABLET	EA	4.5	1.50	6.75
OXYMORPHONE HCL	5 mg	TAB ER 12H	EA	5	3.00	15
OXYMORPHONE HCL	7.5 mg	TAB ER 12H	EA	7.5	3.00	22.5
OXYMORPHONE HCL	10 mg	TAB ER 12H	EA	10	3.00	30
OXYMORPHONE HCL	15 mg	TAB ER 12H	EA	15	3.00	45
OXYMORPHONE HCL	20 mg	TAB ER 12H	EA	20	3.00	60
OXYMORPHONE HCL	30 mg	TAB ER 12H	EA	30	3.00	90
OXYMORPHONE HCL	40 mg	TAB ER 12H	EA	40	3.00	120
OXYMORPHONE HCL	5 mg	TABLET	EA	5	3.00	15
OXYMORPHONE HCL	10 mg	TABLET	EA	10	3.00	30

Appendix B – Proposed Opioid Prior Authorization Criteria

Opioid Analgesics

Goal(s):

- Limit the use of high dose opioid therapy to above-the-line diagnoses that are supported by the medical literature
- Limit the use of non-preferred products
- Promote the safe use of opioids.
  - Opioids have been associated with an increasing proportion of deaths in Oregon and the US.
  - Opioid deaths in Oregon are often associated with concurrent use of other drugs (e.g. other opioids, benzodiazepines, skeletal muscle relaxants)
  - Opioid deaths in Oregon are often associated with patients with a history of drug abuse.
  - Buprenorphine, Fentanyl and Methadone carry FDA Black Box Warnings and have been associated with adverse cardiac effects associated with QTc prolongation and/or life-threatening hypoventalation.
    - This risk is increased with concurrent use of other drugs prolonging the QTc interval or other drugs affecting metablolism of methadone or fentanyl.
  - See Oregon DUR Board newsletter at:
    - http://pharmacy.oregonstate.edu/drug_policy/pages/dur_board/newsletter/articles/volume11/DURV11I2.pdf
    - http://pharmacy.oregonstate.edu/drug_policy/pages/dur_board/newsletter/articles/volume5/DURV5I5.pdf

Initiative:

Long and Short Acting Opioid quantity and dose limits: preferred agents, approved indications, and dose limits.

Length of Authorization:

Up to 6 months

Covered Alternatives:

A list of preferred long acting opioids is available at http://www.oregon.gov/DHS/healthplan/tools_prov/pdl.shtml

Requires a PA:

- All non-preferred opioids and preferred opioids exceeding the dose threshold in the table below, not to exceed a Morphine Equivalent Dose (MED) of 120mg per day.
- Patient with terminal diagnosis, hospice, and metastatic neoplasm (ICD9 = 190xx – 199xx) are exempt from the PA requirements.

-Approved Prior Authorizations may be subject to quantity limits

Dosing Threshold adapted from Washington State Agency Medical Directors Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain 2010 (www.agencymeddirectors.wa.gov)

Opioid	Dose threshold	Recommended starting dose for opioid-naïve patients	Considerations
Buprenorphine Transdermal	20mcg/hour (q 7 days)	5mcg/hr patch q 7 days	May increase dose q72 hours patients up to a max of 20mcg/hr q 7 days. Doses >20mcg/hr q7days increase risk of QTc prolongation.
Fentanyl Transdermal	50mcg/hour (q 72 hr)	Use only in opioid-tolerant patients who have been taking ≥ 60mg MED daily for a week or longer	
Hydromorphone	30mg per 24 hours	2mg q 4–6 hours	
Methadone	80mg per 24 hours	2.5-5mg BID – TID	Methadone is difficult to titrate due to its half-life variability. It may take a long time to reach a stable level in the body. Methadone dose should not be increased more frequently than every 7 days. Do not use as PRN or combine with other long-acting (LA) opioids.
Morphine	120mg per 24 hours	Immediate-release: 10mg q 4 hours Sustained-release: 15mg q 12 hours	Adjust dose for renal impairment.
Oxycodone	80mg per 24 hours	Immediate-release: 5mg q 4–6 hours Sustained Release: 10mg q 12 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing acetaminophen (maximum dose = 4000mg/day x <10day or 2500mg/day for 10 days or more)
Oxymorphone	40mg per 24 hours	Immediate-release: 5–10mg q 4–6 hours Sustained Release: 10mg q 12 hours	**Use with extreme caution due to potential fatal interaction with alcohol or medications containing alcohol**.

Dosing Threshold for select short acting opioids

Opioid	Dose threshold	Considerations
Codeine	800mg/day	
Hydrocodone	120mg/day	Dosing limits based on combinations ingredients (e.g. acetaminophen, ibuprofen) may lower the maximum daily dose dictated by morphine equivalents

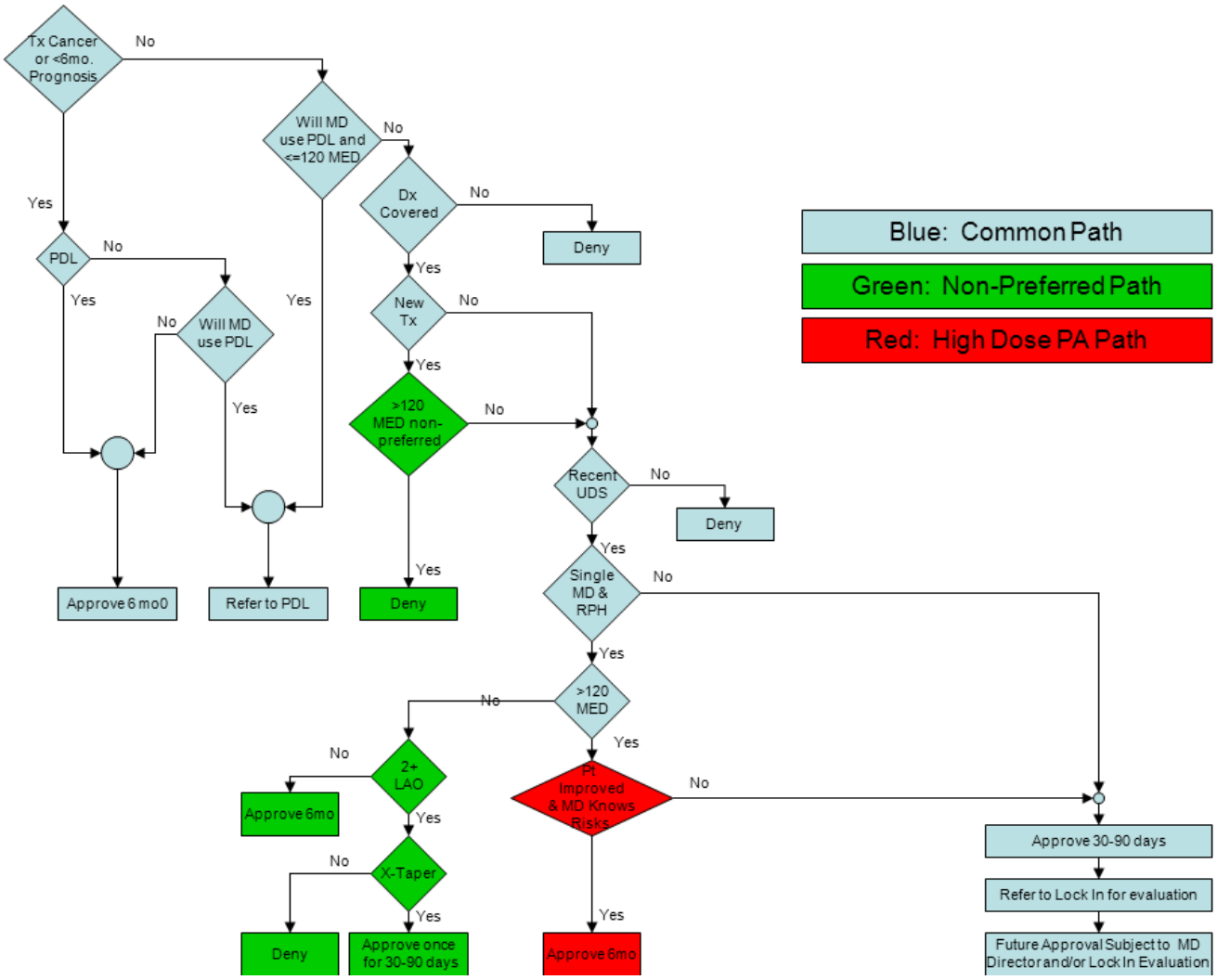
Common indications OHP does not cover:*	ICD9 Codes
Disorders of soft tissue (including Fibromyalgia)	*729.0-729.2,* *729.31-729.39,* *729.4-729.9,* *V53.02*
Acute and chronic disorders of spine without one of the following neurologic impairments: a. Reflex loss b. Dermatomal muscle weakness c. Dermatomal sensory loss d. EMG or NCV evidence of nerve root impingement e. Cauda equina syndrome f. Neurogenic bowel or bladder	*721.0* *721.2-721.3* *721.7-721.8* *721.90* *722.0-722.6* *722.8-722.9* *723.1* *723.5-723.9* *724.1-724.2* *724.5-724.9* *739* *839.2* *847*

*Covered diagnoses are dependent on funding levels. A list of currently funded diagnoses can be found at http://www.oregon.gov/OHA/OHPR/HSC/current_prior.shtml

Approval Criteria		
1. What is the patient's diagnosis?	Record ICD9	
2. Is the patient being treated for any of the following: a. Oncology pain (ICD-9 338.3) b. Terminal diagnosis (<6 months) c. Hospice care	**Yes**: Go to #3	**No**: Go to #5
3. Is the requested medication a preferred agent?	**Yes:** Approve for up to 6 months	**No**: Go to #4
4. Will the prescriber consider a change to a preferred product?	**Yes**: Inform provider of covered alternatives in class.	**No**: Approve for up to 6 months
5. Will the prescriber consider a change to a preferred product not to exceed 120mg MED?	**Yes**: Inform provider of covered alternatives in class.	**No:** Go to #6
6. Is the diagnosis covered by the OHP?	**Yes**: Go to #7	**No:** Pass to RPh, Deny (Not Covered by the OHP)
7. Is this new therapy (i.e. no previous prescription for the same drug, same dose last month)?	**Yes**: Go to #8	**No**: Go To #10
8. Does the total daily opioid dose exceed 120mg MED?	**Yes: Pass to RPh, Deny** (Medical Appropriateness) In general, the total dose of opioid should not exceed 120mg MED Risks substantially increase at doses at or above 100mg MED. Alternatives: Preferred NSAIDs or LAOs @ doses less than 120mg MED.	**No**: Go to #9
9. Has the patient had a recent urinary drug screen (within the past 90 days)?	**Yes**: Go to #10	**No**: Pass to RPH: Deny (Medical Appropriateness) Recommend Urine Drug Screen
10. Is the patient seeing a single prescribing practice & pharmacy for pain treatment (short and long acting opioids)?	**Yes**: Go To #11	**No:** <u>Approve 30-90 days;</u> Refer to Rx Lock-In program for evaluation. Further approvals pending RetroDUR / Medical Director review of case.
11. Does the total daily opioid dose exceed 120mg MED?	**Yes**: Go to #12	**No:** Go to #13

12. Can the prescriber provide documentation of sustained improvement in both function and pain AND the patient is not on concurrent benzodiazepines or other LAO?	**Yes: Approve up to 6 months.** **Quantity Limits Apply, e.g.:** Avinza®: 1 dose / day Butrans®: 1 patch / week Embeda®: 2 doses / day Exalgo®: 1 dose / day Fentanyl: 1 patch / 72 hours Kadian®: 2 doses / day Opana XR®: 2 doses / day Oxycodone ER: 2 doses / day	**No:** Approve 30-90 days to allow for potential tapering of dose. Refer to Rx Lock-In program for evaluation. Further approvals pending RetroDUR / Medical Director review of case.
13. Is the patient concurrently on more than one long-acting opioid (e.g. fentanyl patches, methadone, or long-acting morphine, long-acting oxycodone, long-acting oxymorphone)?	**Yes**: Go to #14	**No**: Approve for up to 6 months
14. Is the duplication due to tapering or switching products? The concurrent use of multiple long-acting opioids is not recommended unless tapering and switching products. Consider a higher daily dose of a single long-acting opioid combined with an immediate release product for breakthrough pain.	**Yes**: Approve for 30-90 days at which time duplication LAO therapy will no longer be approved.	**No: Deny** (Medical Appropriateness) **May approve for taper only.** Refer to Rx Lock-In program for evaluation. If necessary, inform prescriber of provider reconsideration process.

Appendix C – Graphical representation of Opioid Prior Authorization Criteria



References

[1]Oregon State University College of Pharmacy Drug Utilization Research and Management Group. Drug Use Evaluation: Long Acting Opioids (LAO). 2010.

[2] The American Pain society/American Academy of Pain Medicine. Guidelines for the use of chronic opioid therapy in chronic non-cancer pain. http://www.ampainsoc.org/pub/pdf/LBPEvideREv.pdf

[3] Chou R, Fanciullo G, Fine P et al. Clinical Guidelines for the Use of chronic opioid therapy in chronic noncancer pain. The Journal of Pain 2009; 10:113-130.

[4] Edlund MJ, Steffick D, Hudson T, Harris KM, Sullivan M. Risk factors for clinically recognized opioid abuse and dependence among veterans using opioids for chronic non-cancer pain. Pain 2007;129:355-362.

[5] Sullivan MD; Edlund MJ, Zhang L, et al. Association Between Mental Health Disorders, Problem Drug Use, and Regular Prescription Opioid Use Arch Intern Med. 2006;166:2087-2093.

[6] Sullivan, MD, Edlund, MJ, Steffick, D, Unutzer, J. Regular use of prescribed opioids: association with common psychiatric disorders. Pain 2005;119:95-103.

[7] Executive Office of the President of the United States. Epidemic: Responding to America's Prescription Drug Abuse Crisis. Published 2011.

[8] Prescription Painkiller Overdoses in the US. CDC VitalSigns November 2011. Accessed 12/19/2011 at http://www.cdc.gov/vitalsigns/PainkillerOverdoses/index.html

[9] Drug Diversion in the Medicaid Program: State Strategies for Reducing Prescription Drug Diversion in Medicaid. August 2011.

[10] OHP FFS Average Cost PMPM Top 30 Drug Class – Third Quarter 2011. Accessed on 12/8/2011 at http://pharmacy.oregonstate.edu/drug_policy/index.php?nav=reports

[11] OHP FFS Average Cost PMPM Top 40 Drugs (brand name) - Third Quarter 2011. Accessed on 12/8/2011 at http://pharmacy.oregonstate.edu/drug_policy/index.php?nav=reports

[12] NUCYNTA® (tapentadol) immediate-release oral tablets. Package Insert. Janssen Pharmaceuticals, Inc. 2009. Downloaded 12/19/2011 from http://www.nucynta.com/sites/default/files/pdf/Nucynta-PI.pdf

[13] Webster LR, Webster RM. Predicting Aberrant behaviors in opioid-treated patients: preliminary validation of the Opioid Risk Tool. Pain Med. 2005;6:432-42.