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*Editors Note: Oxycontin use and abuse has recently been the subject of many headlines in national publications. State and local authorities as well as the DEA are increasingly concerned about the inappropriate use and diversion of this medication.*

## Opioids: Concerns about the place and need for oxycodone in chronic pain.

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In light of the recent Newsweek article entitled "Playing with PAIN KILLERS," prescription pain medications have received a lot of sensational media concerning the abuse of these medications. In particular, oxycodone was cited as one major drug of concern due to allegations that entire communities have succumbed to the addictive properties of this medication and are now at its mercy. In fact some physicians, who may already be reluctant to prescribe such potent pain killers for outpatient use, are now questioning the place and need for oxycodone in pain therapy. One physician stated that he had seen reports about the illicit use of oxycodone and that half of the manufacturer's sales are due to illicit use. The fact is that the illicit use of oxycodone and other pain medications is concerning, but there still remains a therapeutic place and need for the medication in clinical pain management.

The primary principle of chronic pain management is a multidisciplinary team approach. The approach incorporates pharmacological management, physical therapy, psychological help, and various support systems such as family and spiritual constructs. Narcotics are useful for alleviating pain when integrated into a rehabilitative model using a multidisciplinary approach to

pain management. This may include opioid rotation or substitution to provide adequate relief. Last, constant re-evaluation of the therapy is necessary to properly control pain and possible side effects and individualization of therapy is always required.

Appropriate responsiveness to narcotic analgesics can be influenced by several factors. These include the prevalence of intractable side effects, toxicity due to metabolites, the progression to tolerance, and individual factors affecting pharmacokinetics and dynamics that in turn affects the drug's efficacy. Consequently, the most commonly cited indication for switching opioids is poor pain control with uncontrollable or unacceptable adverse reactions due to toxicity or tolerance. Studies on the topic of opioid rotation produce favorable results with respect to improvement of pain control and alleviation of adverse effects. Oxycodone's place and need in pain therapy is directly related to this concept and has been shown to be efficacious in many clinical situations.

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Wyoming Medicaid Oxycontin Use Jan-Dec 2000

NDC	NDC Description	# OF PAT	# OF RXs	TOT COST	COST/PAT	COST/RX
59011010010	OXYCONTIN 10MG TABLET SA	131	354	\$25,693.01	\$196.13	\$72.58
59011010025	OXYCONTIN 10MG TABLET SA	1	5	\$148.69	\$148.69	\$29.74
59011010310	OXYCONTIN 20MG TABLET SA	136	581	\$83,162.41	\$611.49	\$143.14
59011010325	OXYCONTIN 20MG TABLET SA	1	1	\$74.99	\$74.99	\$74.99
59011010510	OXYCONTIN 40MG TABLET SA	41	149	\$34,035.60	\$830.14	\$228.43
59011010710	OXYCONTIN 80MG TABLET SA	7	35	\$12,407.22	\$1,772.46	\$354.49

...Oxycontin continued

Oxycodone's place in pain management therapy stems from the efficacy of the practice of opioid rotation. Oxycodone has been used in many studies evaluating the practice and efficacy of opioid rotation and has been proven to have a place in pain management. This has been evaluated by direct studies and can be applied in theory. One study in particular showed that oxycodone is advantageous for reducing delirium associated with opioid use in terminal patients. Oxycodone will also be a viable alternative in any case where morphine is no longer effective due to toxicity, tolerance, or adverse effects. Some may argue that oxycodone would produce the same kind of problems as morphine because it is partially metabolized to morphine by O-demethylation, but the major metabolite from the reaction is oxymorphone. Thus, oxycodone's place in pain management is related to the need for opioid rotation, the possible abolition of side effects, the low occurrence of cross sensitivity, and improvement of pain control.

References available on request.

*In Maine, all patients that do not have a cancer diagnosis or are institutionalized are subject to the following prior authorization criteria for*

*Oxycontin:*

- ◆ If use is greater than or equal to 320 mg/day there must be documented medical necessity.
- ◆ Two different long acting narcotics failed/not tolerated.
- ◆ Evidence of full pain evaluation documented.
- ◆ Pain Program evaluation (see form) supporting Oxycontin use.



**State of Maine Department of Human Services  
PRIOR AUTHORIZATION FORM  
NARCOTICS PA (continued)**

Chronic, Noncancer pain opioid criteria: Chart documentation to satisfy the following must be supplied:

Evaluation of Patient

- Pain HX, impact on social, occupational, physical, psychological function
- Review prior diagnostic studies, consults, therapies, surgeries . . .
- Review medical, psychiatric, and substance abuse HX, coexisting conditions
- Directed physical exam
- Failure of reasonable pain management choices such as physical therapy, cognitive behavioral techniques, and medical techniques
- Failure of at least two non-opioid adjuvant drugs to replace, reduce opioids (anticonvulsants, tricyclics, steroids, NSAID, etc.)

Treatment plan/objectives

- Working DX and indications for opioids
- Outline measurable outcomes (pain control, ADL's, functional improvements)
- Informed consent on risks/ benefits of opioids
- Conditions discussed under which opioids will be prescribed and discontinued

Periodic Review

- Assess safety/efficacy of treatment (pain ratings, quality of life, side effects . . .)
- Assess compliance and evidence of misuse
- Reassess nature of pain to confirm opioids still indicated
- Follow all other requirements as specified by Board of Licensure in Medicine re: opioids and standard of care
- Strong consideration of drug assays and/or periodic physician supervised Oxycontin<sup>®</sup> dose administration

Consultation

Referral to pain medicine specialist if situation complex or if  $\geq 120$ mg per day of Oxycontin<sup>®</sup> necessary

Referral to addiction specialist if HX of addiction/substance abuse

Referral to psychiatrist/psychologist if significant psychiatric co-morbidity

Proper Documentation

- Evaluation
- DX
- All written scripts
- Overall pain plan
- All consults, relevant report data
- Written instructions, consent, agreements/contracts

Physician Signature: \_\_\_\_\_ Date of Submission: \_\_\_\_\_

### NEW POINT-OF-SALE EDITS

These limits will be effective May 1, 2001.

#### AMBIEN:

- 1) Ambien 5mg limited to 15 tablets maximum in 31 days
- 2) Ambien 10mg limited to 15 tablets maximum in 31 days

#### PROSOM:

- 1) Prosom 1mg limited to 15 tablets maximum in 31 days
- 2) Prosom 2mg limited to 15 tablets maximum in 31 days

#### SONATA:

- 1) Sonata 5mg limited to 15 tablets in 31 days
- 2) Sonata 10mg limited to 15 tablets in 31 days

#### AMERGE:

- 1) Amerge 1mg limited to 22 tablets in 31 days
- 2) Amerge 2.5mg limited to 9 tablets in 31 days

#### ZOMIG:

- 1) Zomig 2.5mg and Zomig ZMT 2.5mg limited to 18 tablets in 31 days
- 2) Zomig 5mg limited to 9 tablets in 31 days

#### MAXALT:

- 1) Maxalt 5mg and Maxalt MLT 6mg limited to 24 tablets in 31 days
- 2) Maxalt 10mg and Maxalt MLT 10mg limited to 12 tablets in 31 days.

*Note: There is no grace period for day supply with these edits. The full quantity must be used before another claim can be transmitted. In other words, if a recipient is prescribed 15 tablets of Ambien 10mg with a 31 day supply, then the recipient will have to wait until the 32nd day to fill another Ambien prescription.*

#### DIC Advertising Expenditures (1999)

Product	Category	Promotional expenditures (\$million)
Claitin	Antihistamine	1368
Phlosec	Proton pump inhibitor	794
Xenical	Anti-obesity	762
Propocia	Antibaldness	71.1
Zytec	Antihistamine	57.1
Lipitor	Anti-hyperlipidemic	55.5
Zyban	Smoking Cessation	53.9
Flonase	Nasal steroid	53.5
Viagra	Erectile dysfunction	53.0
Nasonex	Nasal steroid	52.3
Orth-Triocyclen	Oral contraceptive	50.1
Meridia	Anti-obesity	43.5
Glucophage	Anti-diabetes	43.1
Allegra	Antihistamine	42.8
Valtrex	Antiviral	40.9
Detrol	Bladder Control	39.6
Zocor	Anti-hyperlipidemic	35.0
Prempro	Estrogen replacement	34.7
Zomig	Anti-migraine	34.4
Flovent	Oral inhaled steroid	31.7

### Physician/Pharmacist Counseling

#### note:

Medications to treat insomnia should ONLY be taken on nights when symptoms occur. With the newer agents available, treatment can be tailored to the individual needs of the patient. Historically, those with sleeping difficulties often were instructed to take the medication at bedtime in anticipation of the problem occurring. The current technique would be to take the medication after being unable to fall asleep at bedtime or to return to sleep after awakening during the night. Waiting until sleeplessness occurs allows the patient to try to sleep naturally and avoids the routine use of medication. In the nursing home, this means waiting for after bedtime rounds to administer sleep medication to those patients having difficulty falling asleep. ■

### MEDICATION ERRORS AND

#### PREVENTION

A recent study by Ernst and Grizzle (JAPhA, Vol.41, No. 2, 2001 pg. 192-199) updated Johnson and Bootman's 1995 cost-of-illness model measuring the morbidity and mortality associated with drug related problems. They found that since 1995, the costs associated with drug related problems have more than doubled to an estimated annual U.S. average of \$177.4 billion. The primary contributors to the total cost were hospital admissions and long term care admissions. Computerized patient records and a coordinated continuum of care will be necessary to prevent drug related problems.

With increasing time and workload pressures, what can health care professionals do to reduce the occurrence of medical errors? The National Coordinating Council for Medication Error Reporting and Prevention has recommended some simple criteria to be followed by those health care providers who write prescriptions:

1. All prescriptions must be legible. Since handwriting has always created problems of legibility, prescribers should move to a direct, computerized order entry system.
2. Prescription orders should include a brief notation of the medication's purpose unless considered inappropriate by the prescriber.
3. All prescription orders should be written in the metric system except for therapies that use standard units such as insulin, vitamins, etc. The term "units" should be spelled out rather than written as the letter "U".
4. The medication order should always include drug name, exact metric weight or concentration, and dosage form.
5. A leading zero should always precede a decimal expression of less than one. A terminal or trailing zero should never be used after a decimal.
6. Prescribers should avoid the use of abbreviations, including those for drug names and Latin directions for use.

Pharmacists need to actively talk to their patients, ensuring that they understand the

Article continued on next page...

## ***RETURN SERVICE REQUESTED***

medications they are taking. The four simple questions the pharmacist should ask every patient, regardless of whether the prescription is new or a refill are:

1. What did the doctor tell you the medication was for?
2. How did the doctor tell you to take the medication?
3. What side effects did the doctor tell you to expect?
4. What questions do you have for me? ■



### **Proton Pump Inhibitors**

With the patent on Prilosec scheduled to expire later this year<sup>1</sup>, Astra Zeneca has introduced a new proton pump inhibitor, Nexium, to the marketplace. It is a good time to review these medications and their costs.

There are now five proton pump inhibitors (PPIs) on the market, Prevacid (lansoprazole), Prilosec (omeprazole), Protonix (pantoprazole), Aciphex (rabeprazole) and Nexium (esomeprazole).

PPIs are used for the treatment of erosive esophagitis, ulcers and gastroesophageal reflux disease (GERD). PPIs are antisecretory drugs that suppress gastric acid secretion by inhibiting the “proton pump” in the lumen, blocking the final step of acid production.

Counseling hints: PPIs should be taken before eating (except Protonix, which may be taken with food).<sup>3</sup> The preferred administration time is in the morning, about 30 minutes before breakfast. If a second dose is required, it should be taken 10-12 hours after the morning dose, 30 minutes before eating<sup>2</sup>. PPIs must be swallowed whole, except Prevacid. Prevacid capsules may be opened but granules must not be crushed or chewed. Granules may be sprinkled in one tablespoon of applesauce,

Ensure pudding, cottage cheese, yogurt, or strained pears and swallowed immediately. Patients may also empty Prevacid capsules into 2 ounces of orange or tomato juice, mix well and swallow immediately. To insure the entire drug is given, the glass should be rinsed with >2 ounces of juice and this juice swallowed also. Antacids may be taken with PPIs.<sup>3</sup>

1 FDA Electronic Orange Book (<http://www.fda.gov/cder/ob/default.htm>)

2 Welage L.S, Berardi R.R. Evaluation of Omeprazole, Lansoprazole, Pantoprazole and Rabeprazole in the Treatment of Acid-Related Disease. Journal of the American Pharmaceutical Association. 2000;40(1):52-62.

3 Facts & Comparisons p. 1135-1138b

4 2001 Drug Topics Redbook ■

<b>Drug (manufacturer)</b>	<b>Dosage (For erosive GERD)<sup>1</sup></b>	<b>Cost (AWP) for 30 day course of therapy<sup>4</sup></b>
<i>Prilosec</i> (Astra)	20mg/day	\$124.17
<i>Nexium</i> (Astra)	20mg/day	\$119.90
<i>Protonix</i> (Wyeth)	40mg/day	\$90.00
<i>Aciphex</i> (Janssen)	20mg/day	\$113.99
<i>Prevacid</i> (TAP)	30mg/day	\$119.90