Chronic Pain Management:

Clinical Practice Guidelines & Abuse-deterrent Pharmacotherapy Options

Lynn P. Chen, Pharm.D, MPH
IEHP Pharmaceutical Services
June 2013

Overview

- IEHP Pharmacy Pain Management Program
- Chronic Pain Management Guideline
- Abuse-deterrent Pharmacotherapy Options

Need for a PPM Program: Alarming Trend in Opioid Use

- > 15,000 deaths resulted from opioid overdose in 2008
- Across the U.S., pharmacies received and dispensed the equivalent of 69 tons of pure oxycodone and 42 tons of pure hydrocodone in 2010. The use of oxycodone and hydrocodone in US accounted for > 80% and 99% of the world's consumption, respectively
- DEA has asked FDA to reclassify hydrocodone as a schedule II drug
- Hydrocodone is powerful yet its abuse and overdose potential are easily overlooked

Why is this important?

- If hydrocodone is classified as a schedule II drug, no refill will be allowed unless the patient is seen and given a prescription
- Identification of inappropriate prescribing behavior has led to an increased number of investigations by the DEA

What resources are available to help my practice?

- Understand that pain treatment involves not only medication, but proper assessment, frequent monitoring, and possibly other treatment modalities such as physical therapy
- Review information from credible resources
  - American Pain Society (http://www.americanpainsociety.org/)
  - American Academy of Pain Medicine (http://www.painmed.org/)
  - American Chronic Pain Association (http://www.theacpa.org/)
- Incorporate Pain Management Clinical Practice Guideline into your practice (i.e. IEHP CPG)

IEHP Pharmacy
Pain Management (PPM) Program

- IEHP Pharmacy Department-run review of pain management regimens
- Clinical pharmacist identifies high-risk members and addresses potential inappropriate prescribing patterns
- Assist prescribers in management of chronic pain

PPM Program Member Stratification

- Level 1
  - Members using > than 180 units of short-acting opioids in a month
- Level 2
  - Members taking 4 or > opiate prescriptions in a month for 2 consecutive months OR
  - Members receiving opiate prescriptions from 2 or > physicians in a month for 2 consecutive months
- Level 3 (highest level of severity)
  - Patients using >120 mg morphine equivalent dose (MED) per day

PPM Program Goals

- Facilitate appropriate use of opioid therapies (formulary options, quantity prescribed, dosage)
- Promote use of long-acting (LA) opioids instead of short-acting (SA) opioids for chronic pain patients
- Assist prescribers by identifying members with potential drug-seeking behavior
- Streamline prior authorization process for members monitored under a treatment protocol
- Extend authorizations for long-term therapy

PPM Program Provider Expectations

- Utilization of comprehensive pain management tools
- Adoption of pain contract
- Submission of medical documentation and treatment plan for all members that meet analgesic request requirements and formulary quantity limits

Chronic Pain Management Tools

- Clinical Practice Guideline Elements
  - Opioid Risk Tool (ORT)
  - Pain Management Contract
  - Pain Assessment and Documentation Tool (PADT)
  - Current Opioid Misuse Measure (COMM)
- Opioid Analgesic Request Requirements
- Formulary Quantity Limits (QL)
- Pain Assessment and Treatment Plan

Opioid Risk Tool (ORT)

- Predict risk for drug-seeking behaviors related to opioid therapy use
- Self-administered or completed by provider
- Risk assigned based on ORT score
  - Low (0-3)
  - Medium (4-7)
  - High (≥ 8)
- More risk factors correlate with increased probability for opioid abuse
- Available online at www.opioidrisk.com

Opioid Risk Tool (ORT)

Patient Form

Name _____ Date _____

Mark each box that applies		Female	Male
1. Family history of substance abuse	▪ Alcohol ▪ Illegal drugs ▪ Prescription drugs	[ ] [ ] [ ]	[ ] [ ] [ ]
2. Personal history of substance abuse	▪ Alcohol ▪ Illegal drugs ▪ Prescription drugs	[ ] [ ] [ ]	[ ] [ ] [ ]
3. Age (mark box if 16-45 years)		[ ]	[ ]
4. History of preadolescent sexual abuse		[ ]	[ ]
5. Psychological disease	▪ Attention-deficit/ hyperactivity disorder, obsessive-compulsive disorder, bipolar disorder, schizophrenia ▪ Depression	[ ] [ ]	[ ] [ ]

Identification

Pain Management Contract

Commitment

SAMPLE FOR ADAPTATION AND REPRODUCTION
ON PHYSICIAN LETTERHEAD

PLEASE CONSULT WITH YOUR ATTORNEY

Long-term Controlled Substances Therapy for Chronic Pain

SAMPLE AGREEMENT

*A consent form from the **American Academy of Pain Medicine***

The purpose of this agreement is to protect your access to controlled substances and to protect our ability to prescribe for you.

The long-term use of such substances as opioids (narcotic analgesics), benzodiazepine tranquilizers, and barbiturate sedatives is controversial because of uncertainty regarding the extent to which they provide long-term benefit. There is also the risk of an addictive disorder developing or of relapse occurring in a person with a prior addiction. The extent of this risk is not certain.

Because these drugs have potential for abuse or diversion, strict accountability is necessary when use is prolonged. For this reason the following policies are agreed to by you, the patient, as consideration for, and a condition of, the willingness of the physician whose signature appears below to consider the initial and/or continued prescription of controlled substances to treat your chronic pain.

1. All controlled substances must come from the physician whose signature appears below or, during his or her absence, by the covering physician, unless specific authorization is obtained for an exception. (Multiple sources can lead to untoward drug interactions or poor coordination of treatment.)
2. All controlled substances must be obtained at the same pharmacy, where possible. Should the need arise to change pharmacies, our office must be informed. The pharmacy that you have selected is:

   _____ phone: _____.
3. You are expected to inform our office of any new medications or medical conditions, and of any adverse effects you experience from any of the medications that you take.
4. The prescribing physician has permission to discuss all diagnostic and treatment details with dispensing pharmacists or other professionals who provide your health care for purposes of maintaining accountability.
5. You may not share, sell, or otherwise permit others to have access to these medications.
6. These drugs should not be stopped abruptly, as an abstinence syndrome will likely develop.
7. Unannounced urine or serum toxicology screens may be requested, and your cooperation is required. Presence of unauthorized substances may prompt referral for assessment for addictive disorder.

Pain Management Contract

Commitment

8. Prescriptions and bottles of these medications may be sought by other individuals with chemical dependency and should be closely safeguarded. It is expected that you will take the highest possible degree of care with your medication and prescription. They should not be left where others might see or otherwise have access to them.

9. Original containers of medications should be brought in to each office visit.

10. Since the drugs may be hazardous or lethal to a person who is not tolerant to their effects, especially a child, you must keep them out of reach of such people.

11. Medications may not be replaced if they are lost, get wet, are destroyed, left on an airplane, etc. If your medication has been stolen and you complete a police report regarding the theft, an exception may be made.

12. Early refills will generally not be given.

13. Prescriptions may be issued early if the physician or patient will be out of town when a refill is due. These prescriptions will contain instructions to the pharmacist that they not be filled prior to the appropriate date.

14. If the responsible legal authorities have questions concerning your treatment, as might occur, for example, if you were obtaining medications at several pharmacies, all confidentiality is waived and these authorities may be given full access to our records of controlled substances administration.

15. It is understood that failure to adhere to these policies may result in cessation of therapy with controlled substance prescribing by this physician or referral for further specialty assessment.

16. Renewals are contingent on keeping scheduled appointments. Please do not phone for prescriptions after hours or on weekends.

17. It should be understood that any medical treatment is initially a trial, and that continued prescription is contingent on evidence of benefit.

18. The risks and potential benefits of these therapies are explained elsewhere [and you acknowledge that you have received such explanation].

19. You affirm that you have full right and power to sign and be bound by this agreement, and that you have read, understand, and accept all of its terms.

_____ _____

Physician Signature Patient Signature

_____ _____

Date Patient Name (Printed)

Approved by the AAPM Executive Committee on April 2, 2001.

AAPM
4700 W. Lake Avenue
Glenview, IL 60025-1485
847/375-4731 Fax 847/375-6477
E-mail info@painmed.org
Web site http://www.painmed.org/

Monitoring

PROGRESS NOTE
Pain Assessment and Documentation Tool (PADT™)

Patient Stamp Here

Patient Name: _____ Record #: _____

Assessment Date: _____

Current Analgesic Regimen

Drug name	Strength (eg, mg)	Frequency	Maximum Total Daily Dose

The PADT is a clinician-directed interview; that is, the clinician asks the questions, and the clinician records the responses. The Analgesia, Activities of Daily Living, and Adverse Events sections may be completed by the physician, nurse practitioner, physician assistant, or nurse. The Potential Aberrant Drug-Related Behavior and Assessment sections must be completed by the physician. Ask the patient the questions below, except as noted.

Analgesia

If zero indicates "no pain" and ten indicates "pain as bad as it can be," on a scale of 0 to 10, what is your level of pain for the following questions?

1. What was your pain level on average during the past week? (Please circle the appropriate number)

No Pain 0 1 2 3 4 5 6 7 8 9 10 **Pain as bad as it can be**

2. What was your pain level at its worst during the past week?

No Pain 0 1 2 3 4 5 6 7 8 9 10 **Pain as bad as it can be**

3. What percentage of your pain has been relieved during the past week? (Write in a percentage between 0% and 100%.) _____

4. Is the amount of pain relief you are now obtaining from your current pain reliever(s) enough to make a real difference in your life?
❑ Yes ❑ No

5. **Query to clinician**: Is the patient's pain relief clinically significant?
❑ Yes ❑ No ❑ Unsure

Activities of Daily Living

Please indicate whether the patient's functioning with the current pain reliever(s) is Better, the Same, or Worse since the patient's last assessment with the PADT.* (Please check the box for Better, Same, or Worse for each item below.)

	Better	Same	Worse
1. Physical functioning	❑	❑	❑
2. Family relationships	❑	❑	❑
3. Social relationships	❑	❑	❑
4. Mood	❑	❑	❑
5. Sleep patterns	❑	❑	❑
6. Overall functioning	❑	❑	❑

* If the patient is receiving his or her first PADT assessment, the clinician should compare the patient's functional status with other reports from the last office visit.

Monitoring

PROGRESS NOTE
Pain Assessment and Documentation Tool (PADT™)

Adverse Events

1. Is patient experiencing any side effects from current pain reliever(s)? ❑ Yes ❑ No

Ask patient about potential side effects:

	None	Mild	Moderate	Severe
a. Nausea	❑	❑	❑	❑
b. Vomiting	❑	❑	❑	❑
c. Constipation	❑	❑	❑	❑
d. Itching	❑	❑	❑	❑
e. Mental cloudiness	❑	❑	❑	❑
f. Sweating	❑	❑	❑	❑
g. Fatigue	❑	❑	❑	❑
h. Drowsiness	❑	❑	❑	❑
i. Other _____	❑	❑	❑	❑
j. Other _____	❑	❑	❑	❑

2. Patient's overall severity of side effects?
❑ None ❑ Mild ❑ Moderate ❑ Severe

Potential Aberrant Drug-Related Behavior
This section must be completed by the physician.

Please **check** *any of the following items that you discovered during your interactions with the patient.* Please note that some of these are directly observable (eg, appears intoxicated), while others may require more active listening and/or probing. Use the "Assessment" section below to note additional details.

- ❑ Purposeful over-sedation
- ❑ Negative mood change
- ❑ Appears intoxicated
- ❑ Increasingly unkempt or impaired
- ❑ Involvement in car or other accident
- ❑ Requests frequent early renewals
- ❑ Increased dose without authorization
- ❑ Reports lost or stolen prescriptions
- ❑ Attempts to obtain prescriptions from other doctors
- ❑ Changes route of administration
- ❑ Uses pain medication in response to situational stressor
- ❑ Insists on certain medications by name
- ❑ Contact with street drug culture
- ❑ Abusing alcohol or illicit drugs
- ❑ Hoarding (ie, stockpiling) of medication
- ❑ Arrested by police
- ❑ Victim of abuse

Other: _____

Assessment: (This section must be completed by the physician.)

Is your overall impression that this patient is benefiting (eg, benefits, such as pain relief, outweigh side effects) from opioid therapy? ❑ Yes ❑ No ❑ Unsure

Comments: _____

Specific Analgesic Plan:

- ❑ Continue present regimen
- ❑ Adjust dose of present analgesic
- ❑ Switch analgesics
- ❑ Add/Adjust concomitant therapy
- ❑ Discontinue/taper off opioid therapy

Comments: _____

Date: _____ Physician's signature: _____

Current Opioid Misuse Measure (COMM)

- Brief patient self-assessment tool developed by pain management clinicians
- Identifies key issues to determine if patients already on long-term opioid treatment are exhibiting aberrant medication-related behaviors
- 6 Key Issues
  - Signs & Symptoms of Intoxication
  - Emotional Volatility
  - Evidence of Poor Response to Medications
  - Addiction
  - Healthcare Use Patterns
  - Problematic Medication Behavior

COMM

COMM™

Please answer each question as honestly as possible. Keep in mind that we are only asking about the **past 30 days**. There are no right or wrong answers. If you are unsure about how to answer the question, please give the best answer you can.

Please answer the questions using the following scale:	Never 0	Seldom 1	Sometimes 2	Often 3	Very Often 4
1. In the past 30 days, how often have you had trouble with thinking clearly or had memory problems?	O	O	O	O	O
2. In the past 30 days, how often do people complain that you are not completing necessary tasks? (i.e., doing things that need to be done, such as going to class, work or appointments)	O	O	O	O	O
3. In the past 30 days, how often have you had to go to someone other than your prescribing physician to get sufficient pain relief from medications? (i.e., another doctor, the Emergency Room, friends, street sources)	O	O	O	O	O
4. In the past 30 days, how often have you taken your medications differently from how they are prescribed?	O	O	O	O	O
5. In the past 30 days, how often have you seriously thought about hurting yourself?	O	O	O	O	O
6. In the past 30 days, how much of your time was spent thinking about opioid medications (having enough, taking them, dosing schedule, etc.)?	O	O	O	O	O
7. In the past 30 days, how often have you been in an argument?	O	O	O	O	O
8. In the past 30 days, how often have you had trouble controlling your anger (e.g., road rage, screaming, etc.)?	O	O	O	O	O
9. In the past 30 days, how often have you needed to take pain medications belonging to someone else?	O	O	O	O	O
10. In the past 30 days, how often have you been worried about how you're handling your medications?	O	O	O	O	O
11. In the past 30 days, how often have others been worried about how you're handling your medications?	O	O	O	O	O
12. In the past 30 days, how often have you had to make an emergency phone call or show up at the clinic without an appointment?	O	O	O	O	O
13. In the past 30 days, how often have you gotten angry with people?	O	O	O	O	O
14. In the past 30 days, how often have you had to take more of your medication than prescribed?	O	O	O	O	O
15. In the past 30 days, how often have you borrowed pain medication from someone else?	O	O	O	O	O
16. In the past 30 days, how often have you used your pain medicine for symptoms other than for pain (e.g., to help you sleep, improve your mood, or relieve stress)?	O	O	O	O	O
17. In the past 30 days, how often have you had to visit the Emergency Room?	O	O	O	O	O

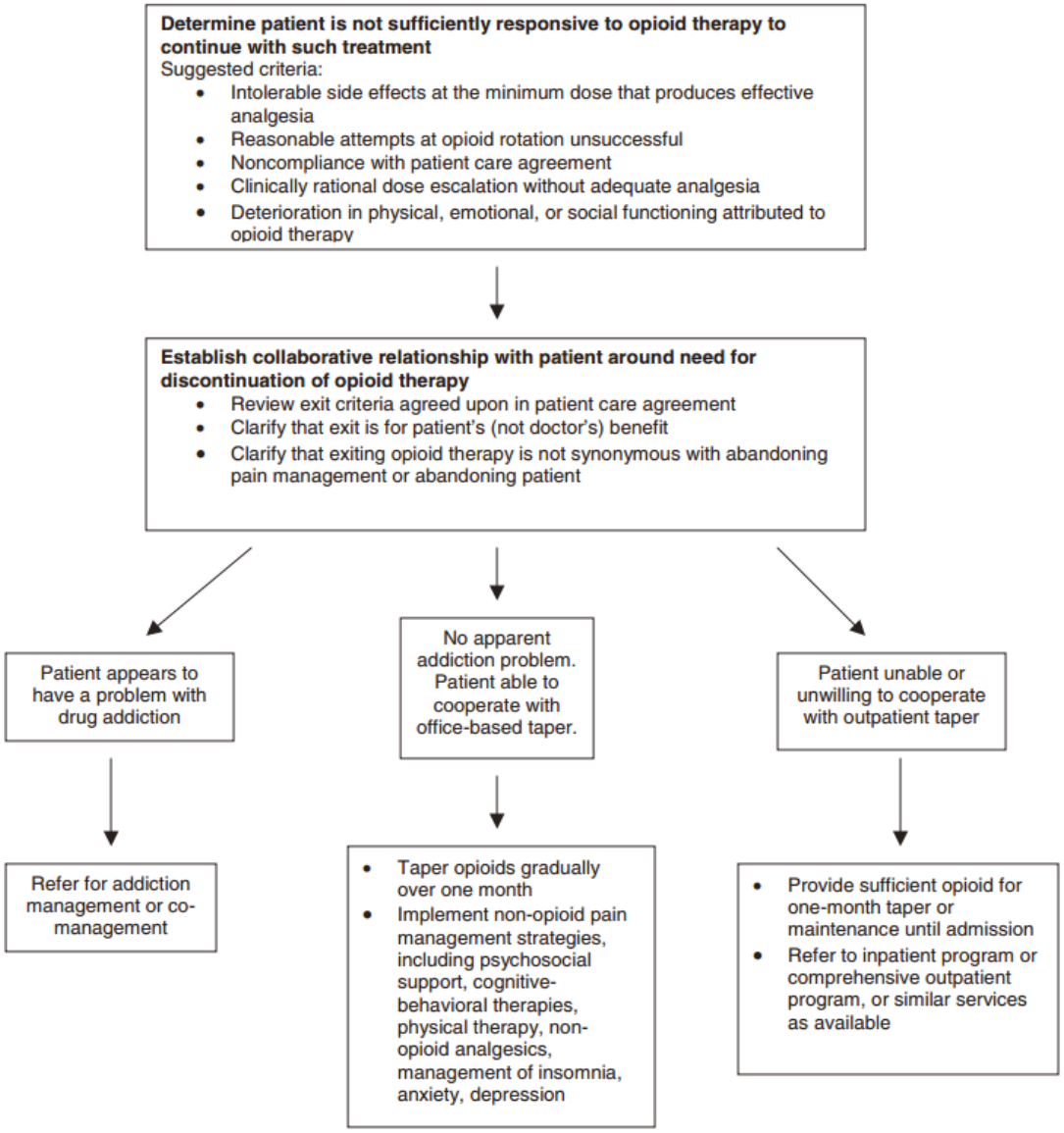
COMM

- Sensitive test
- Intended to over-identify misuse of therapy rather than mislabel someone as abusing therapy
- Add rating of all questions
  - Score ≥ 9 is positive
  - Identifies 77% of those considered high risk
  - Considered 3x more likely to be misusing medication
- Ideal for helping clinicians monitor aberrant medication-related behaviors over the course of treatment

Discontinuation

Exit Strategy Guide for Discontinuation of Opioid Therapy

The possibility of subsequent discontinuation from opioid therapy should be discussed with the patient at the time that opioid therapy is initiated.



Opioid Analgesic Request Requirements

Level	Condition	Recommended Action for Providers	Required Medical Documentation
I	CIII-CIV: w/in quantity limits (QL)	1. Pain assessment 2. Treatment plan	None
II	CII-CIII: Non-formulary (NF) or > QL	1. Pain assessment 2. Treatment plan 3. Pain contract	1. Pain assessment 2. Treatment plan 3. Pain contract

Formulary Quantity Limits

Brand Name	Generic Name	Schedule	QL/30 days
Tylenol w/Codeine	Codeine/APAP	III	#90
Empirin w/Codeine	Codeine/Aspirin		#90
Lorcet, Lortab, Norco	Hydrocodone/APAP		#240
Duragesic	Fentanyl	II	#10
MS Contin, Avinza, Kadian	Morphine		#60
Percocet, Percodan	Oxycodone/APAP		#240
Oxycontin	Oxycodone		For patients w/cancer
Toradol	Ketorolac		#20

Pain Assessment & Treatment Plan

Patient Name: _____ DOB: _____

PER #: _____ Member ID #: _____

Diagnosis

Please provide diagnosis on record:

Pain Assessment

On a scale of 0 - 10, how would you assess the patient's current pain (0 = No pain, 10 Worst Pain). Please circle one:

0 1 2 3 4 5 6 7 8 9 10 Comments: _____

On a scale of 0 - 10, what is the pain scale goal for this patient (*ie. By implementing treatment, how much do you feel you can decrease the patient's pain*)? Please circle one:

0 1 2 3 4 5 6 7 8 9 10 Comments: _____

Is the patient experiencing any side effects from current pain reliever(s)?
(Please circle one): Yes or No. If yes, please explain:

Is the patient exhibiting any potential aberrant drug related behavior (eg. early refills, frequent lost or stolen medications, history of abuse, etc…)?
(Please circle one): Yes or No. If yes, please explain:

Current Analgesic Regimen

Drug Name	Strength (eg. mg, gm, ml)	Frequency
1.		
2.		
3.		
4.		

Treatment Plan

Please check one:	*Comments:*
☐ Continue present regimen ☐ Adjust dose of present regimen ☐ Switch analgesic ☐ Add/adjust concomitant therapy ☐ Discontinue/taper off opiod therapy	

Requested Length of Authorization

Please check one:	*Please provide reason for requests greater than 1 month:*
☐ 1 month ☐ 3 months ☐ 6 months	

Please Sign and Fax to IEHP (909) – 890 -2058. We appreciate your Prompt Response.

Physician Name (Print): _____ Physician Signature: _____

Date: _____

ABUSE-DETERRENT PHARMACOTHERAPY OPTIONS

Overview

- Oxecta
- Oxycontin (Reformulated)
- Opana ER
- Exalgo

Oxecta

- Tamper-resistant, immediate-release oxycodone 5 mg or 7.5 mg tablet
- Formulated with patented Aversion Technology
- Forms viscous gel formation if in contact with water
- Sodium laurel sulfate serves as nasal irritant if tablet crushed and snorted
- Cost: $2.67/tablet → ~$320-$961/month

Oxycontin (Reformulated)

- Controlled & extended-release oxycodone tablets
- On 4/16/2013, received FDA-approved labeling to confirm reformulated product as having abuse-deterrent properties
- Hardened matrix that resists crushing or dissolution in liquids to deter nasal or IV use
- Forms viscous hydrogel that cannot be easily prepared for injection
- Cost: $2.13/tablet → ~$129/month

Opana ER

- Extended-release oxymorphone tablet
- Crush-resistant
- Strengths: 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg
- Cost: $3.63/tablet → ~$218/month

Exalgo

- **O**smotic extended-**R**elease **O**ral delivery **S**ystem (OROS) hydromorphone
- Osmotically-active bilayer core enclosed in semipermeable tablet shell membrane
- Delivered at constant rate over 24 hrs
- For opiate-tolerant patients only
- Cost: $10/tablet

Summary

Drug	Unit Price	Formulary Status
Oxecta (Oxycodone IR)	**$2.67**	**NF**
Oxycontin (Oxycodone CR & ER)	**$2.13**	**NF**
Opana ER (Oxymorphone)	**$3.63**	**NF**
Exalgo (OROS hydromorphone)	**$10**	**NF**
Tramadol (Ultram)	$0.10	F
Codeine/APAP (Tylenol #3)	$0.10-$0.20	F
Hydrocodone/APAP (Vicodin, Norco, Lorcet, Lortab)	$0.05	F
Oxycodone/APAP (Percocet)	$0.23	F
Morphine ER (MS Contin, Kadian, Avinza)	$0.35-$0.70	F

Criteria for Use of Abuse-Deterrent Options

- Cannot be used as initial therapy
- For the following members:
  - Identified as high-risk for opioid abuse or misuse **AND**
  - Will be evaluated and monitored by a pain management specialist
- Member has been considered for program to manage opioid dependence and withdrawal if appropriate

Key to Success: Appropriate Use of Pain Medications

- **Steps for Success**
  - Assess patient for treatment
  - Define expectations of the treatment protocol (review treatment goals, pain contract, patient's responsibilities, monitoring parameters)
  - Understand pharmacologic treatment principles (use of LA opioids for chronic pain control and reserving SA opioids for breakthrough pain)
  - Evaluate patient if dosage of therapy exceeds 80 Morphine Equivalent Dose (MED) per day (>120 MED is considered to be high)
  - Refer to pain management specialist (if appropriate)