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Notice of Independent Review Decision

DATE OF REVIEW: 01/26/10

IRO CASE NO.:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Item in dispute:
Methadone:10mg 1 tab 3x daily #90-cervical 90862
Neurontin:600mg 1 tab 3x daily #90-cervical 90862
Ultram:50mg 1-2 tabs 3x daily #90-cervical 90862
Naprosyn:500mg 1-2 tabs 2x daily #60-cervical 90862

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

Board Certified Anesthesiologist/Pain Management

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determination should be:

Denial Upheld

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

1. Clinical records PAC, 09/18/92
2. Clinical records Dr., 03/02/95, 06/28/98
3. Clinical records Dr., 09/10/02, 11/20/03, 01/07/04, 03/03/09, 12/06/05
4. Clinical records M.D., 12/04/03, 12/19/03, 01/22/04, 03/05/04, 12/15/09
5. Chronic pain management treatment notes
6. D.O., 12/19/03
7. RME report Dr. dated 06/20/05, 08/03/06, 08/27/06, 02/24/07, 07/23/07
8. MRI cervical spine dated 08/12/05.
9. Psychological evaluation, 12/05/05, 05/26/06
10. Peer review, 07/12/06, 09/21/08
11. Group, 07/19/06, 07/31/06, 09/08/06, 11/21/06, 01/22/07
12. Addendum to RME report dated 02/24/07.

13. Utilization review determination dated 12/22/09.

14. Utilization review determination dated 01/04/10.
15. **Official Disability Guidelines**

PATIENT CLINICAL HISTORY (SUMMARY):

The employee is a male who is reported to have sustained work related injuries on xx/xx/xx. On this date he was moving large appliances and lifted a large TV screen when he felt pain into the arm. It is reported that he was treated conservatively and ultimately underwent ACDF in 1993. The employee is reported to have had improvement for several years and subsequently began to develop recurrent pain around 2001. In 12/04/03 the employee came under the care of Dr.. The employee's pain is reported to be improved with medications. The employee's previous surgeries include an ACDF from C4-C7 in 1993. Current medications at this time are Lortab and he also takes Robaxin and Bextra. On examination of the cervical spine the employee has guarding, muscle spasm, tenderness, range of motion is decreased. Similar findings are noted in the thoracic and lumbar spine. Provocative testing is negative and DTRs are normal bilaterally. Gait is normal and there is decreased sensation to the right upper extremity in the C8 dermatome. Motor is intact. Records indicate that the employee subsequently underwent a series of cervical epidural steroid injections and was largely treated with oral medications.

The record contains an RME report by Dr. dated 06/20/05. At this time, the employee is reported to be taking Methadone tid with some relief, Neurontin 300 mg tid with some relief, Soma which has provided him relief. He has previously had neck surgery in the form of a fusion. At this time the employee complains of headaches which are worse and pain in the neck which is worse and pain to the right upper extremities. He reports numbness to the side of his neck since surgery and he has tenderness to the right trapezius region. He reports numbness in the ulnar digits. His neck and arm pain are reported to be equal. On physical examination his gait was normal. He is able to stand on his heels and toes and he is able to squat and arise. He is able to stand on 1 leg. Head carriage was normal. Shoulder levels are equal. There is tenderness to palpation of the cervical spine into the right trapezius. Range of motion is reduced. Upper extremity motor strength is normal. There is no intrinsic hypothenar or thenar atrophy noted. There is no spasticity, rigidity or flaccidity noted on examination. Upper extremity reflexes were 2+ and symmetric. FCE is reported to have indicated a light physical demand level. She recommends that the employee be referred to Dr. for evaluation to determine if he is a surgical candidate. She recommends making no changes to his prescription medications following evaluation and diagnostic studies.

On 08/12/05 the employee was referred for MRI of the cervical spine. This study notes broad osteophyte disc protrusion complexes measuring 4 mm at C2-3 and C3-4 with mild bilateral neural foraminal narrowing at C2-3 and moderate bilateral neural foraminal narrowing at C3-4. At C4-5 there is a 2 mm central disc protrusion herniation with mild bilateral neural foraminal narrowing and no canal stenosis. At C5-6 and C6-7 there is evidence of a prior fusion with no disc herniation, canal stenosis or neural foraminal

encroachment. At C7-T1 there is a broad 2 mm disc protrusion with mild bilateral neural foraminal narrowing. Additional records indicate that the employee participated in a chronic pain management program in 2006. On 02/24/07 an addendum was submitted by Dr. Dr. reports that in an addendum report dated 08/27/06 she was asked to address areas regarding the psychotherapy and mental health therapy participation and chronic pain management program. She notes that at the time of examination the employee did not comment that he was participating in a chronic pain program. She notes that in her previous RME report it was her opinion that his medications should be weaned given the fact that he has side effects from his prescription medications. She reports that he does need some form of prescription medications and that there needs to be an adjustment made in his medications and subsequently he would only require follow up 1x a quarter. She does not opine that the employee requires individual psychotherapy and notes that he should have been instructed on behavioral management techniques while in the chronic pain management program. Most recent clinical records from Dr. indicate that the employee has had increased headaches for the last 3 days. He has pain in his neck and into his upper extremities. He is reported to have bilateral GON tenderness with no change. The employee subsequently is diagnosed with an acute exacerbation of pain and occipital neuralgia. His Methadone was increased to tid short term and his Neurontin was increased to tid. The employee is reported to be participating in a home exercise program and physical therapy program and he is to be seen in 4 weeks. The employee was subsequently seen in follow up on 02/03/09. It is reported that increasing his Methadone helped. He continues to have headaches and pain in the neck. Current medications are Ultram prn, Methadone 10 mg and Neurontin 1/600 mg tid. It is reported that these medications are helpful for the employee affording him increased function and activities of daily living. The employee's examination is reported to be unchanged and he is assessed with improved pain control.

The employee was seen in follow up on 03/03/09. The employee is reported to be unchanged since his last visit. His medications have not been approved by workers' compensation. His pain is reported to be 3/4/10 of EAS and his medication profile is unchanged. No physical examination is documented. On 04/24/09 the employee was seen in follow up. He is reported to have increased pain secondary to being out of Neurontin. Overall he is reported to be the same and he continues to have pain in the neck. His VAS score is 4/10. No examination is documented. He is reported to have good pain control with his current regimen. The employee was seen in follow up on 05/26/09. He is reported to be worse. He has pain in his neck and into his upper extremities. His pain level is now reported to be 8/10 and his medication profile remains the same. He is reported to have increased cervical paraspinal tenderness with decreased range of motion. His Neurontin was increased to 2400 per day on bad days.

The employee was seen in follow up on 06/23/09. At this time he is reported to have improvement by increasing his Neurontin. His physical examination is unchanged. The records indicate that the employee was continued on this medication profile. Clinical note dated 11/10/09 indicates that the employee had undergone a drug screen for compliance.

On 12/22/09 a request was placed by Dr. for Methadone 10 mg 1 tab 3x daily, Neurontin 600 mg 1 tab 3x daily, Ultram 50 mg 1-2 tabs 3x daily, Naprosyn 500 mg 1-2 tabs 2x daily. This case was reviewed by Dr. who non-certified the request. He reports that based upon the available documentation and ODG guidelines, the request for Methadone and Ultram is not reasonable or medically necessary. He reports that the guidelines state that NSAIDs are recommended as an option for short term symptomatic relief. There are no reported failures of non opioid analgesic regimen for his chronic pain prior to high dose narcotics Methadone in conjunction with Ultram. A letter dated 12/17/09 reported subjective description of improved function with medications and no objective measures were given. He reports that according to ODG, Neurontin is a first line treatment for neuropathic pain however since contact with the provider was not made, the request is recommended as non-certified based on the given documentation. Dr. is Board Certified in Physical Medicine, Rehabilitation and Pain Management.

The case was appealed on 01/04/10. At this time it was reviewed by Dr.. Dr. non-certifies the request. He reports that per the clinical records dated 12/23/09, the employee is currently taking Ultram, Methadone, Naprosyn and Neurontin. He notes that the aforementioned medications are not intended for chronic use. The clinical information provided for the review did not meet practice guidelines for the use of the requested medications as referenced above. He notes that there is no objective documentation regarding functional improvement associated with the requested medications. He reports that measures of control or tapering these said medications to prevent long term unwanted side effects were not provided. As such, the appropriateness, medically necessary and anticipated benefits of the requested medications are not sufficiently substantiated. Additional relevant information is required to establish the medical necessity of the request.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

The request for Methadone, Neurontin, Ultram and Naproxen is not supported by the submitted clinical information. The available clinical records indicate that the employee initially sustained an injury to his cervical spine on 06/02/92. The employee underwent a period of conservative treatment and failed to improve and ultimately underwent a C4-C7 cervical fusion in 1993. The employee is noted to have improved with operative intervention; however,

over time he developed recurrent cervical pain with some suggestion of a radicular component however independent physical examination does not note any significant findings associated with a cervical radiculopathy. Imaging studies clearly indicate that the employee has degenerative disease above and below the previous levels of fusion. The employee has previously participated in a chronic pain management program in 2006. This does not appear to have reduced his requirement for continued use of oral medications. The records as submitted by Dr. do not provide detailed serial physical examinations. There is no documentation supporting that the employee has signed a chronic pain management contract. The record does not provide any objective data from which to establish that the employee is functionally improved on these medications. The data contained in the serial notes is all subjective in nature. As a result, there is insufficient data to establish the medical necessity for continued use of these medications. It should be noted that these medications cannot be abruptly discontinued and the clinical record indicates that on at least two separate occasions, independent reviewers have recommended a tapering or discontinuation of oral medications.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

The 2010 Official Disability Guidelines, 15th edition, The Work Loss Data Institute. Online edition.
Methadone
Recommended as a second-line drug for moderate to severe pain if the potential benefit outweighs the risk. The FDA reports that they have received reports of severe morbidity and mortality with this medication. This appears, in part, secondary to the long and variable half-life of the drug (8-59 hours). Pain relief on the other hand only lasts from 4-8 hours. It may take several days to weeks to obtain adequate pain control. Methadone should only be prescribed by providers experienced in using it. (Clinical Pharmacology, 2008). In addition, the patient should be highly responsible and be made aware of use and effects as listed below.
Pharmcokinetics: Genetic differences appear to influence how an individual will respond to this medication. Following oral administration, significantly different blood concentrations may be obtained. Vigilance is suggested in treatment initiation, conversion from another opioid to methadone, and when titrating the methadone dose. (Weschules 008) (Fredheim 2008)
Adverse effects: Delayed adverse effects may occur due to methadone accumulation during chronic administration. A particular risk factor for mortality is the concomitant use with benzodiazepines, other opioids, and/or alcohol. Systemic toxicity is more likely to occur in patients previously exposed to high doses of opioids. This may be related to tolerance that develops related to the N-methyl-D-aspartate (NMDA) receptor antagonist. Patients may respond to lower doses of methadone than would be expected

based on this antagonism. One severe side effect is respiratory depression (which persists longer than the analgesic effect). Methadone should be given with caution to patients with decreased respiratory reserve (asthma, COPD, sleep apnea, severe obesity). QT prolongation with resultant serious arrhythmia has also been noted. Use methadone carefully in patients with cardiac hypertrophy and in patients at risk for hypokalemia (including those patients on diuretics). Methadone does have the potential for abuse. Precautions are necessary as well for employees in safety sensitive positions, including operation of a motor vehicle.

EKG monitoring: There is no current evidence to firmly advise EKG monitoring when prescribing methadone. Expert opinion includes the use of an EKG for doses of methadone > 100 mg/day or if there are factors that may lead to prolonged QTc intervals (such as underlying cardiac disease). If the QTc interval is > 500 ms methadone should be weaned. (Peng, 2008) Others have suggested EKGs in patients over the age of 40 years and during dose stabilization in “high risk” patients. “High risk” is not well defined but there appears to be a high “tolerance” for EKG monitoring. See also Opioids for general guidelines, as well as specific Methadone (Dolophine®, Methadose®) listing for more information and references.

Steps for prescribing methadone:

(1) *Basic rules*

- Weigh the risks and benefits before prescribing methadone.
- Avoid prescribing 40 mg Methadone tablets for chronic non-malignant pain. This product is only FDA-approved for detoxification and maintenance of narcotic addiction.
- Closely monitor patients who receive methadone, especially during treatment initiation and dose adjustments.

(2) *Know the information that is vital to give the patient:*

- Inform the patient that methadone is not a breakthrough medication.
- Inform the patient that they should not be tempted to take more methadone than prescribed if they are not getting pain relief as this can lead to a dangerous build-up that can lead to death.
- All changes in methadone dose should be made by the treating practitioner.
- The patient should be warned to not use alcohol, benzodiazepines or other CNS depressants (particularly at night) unless specifically prescribed by the treating physician.
- Inform the patient of the potential adverse effects of methadone. These include respiratory depression, irregular heartbeat, dizziness, light-headedness, and/or syncope. An emergency number and/or plan should be given to the patient in case symptoms occur. (FDA, 2006)
- Consider starting methadone early in the week to allow for titration and monitoring.

(3) *Be familiar with the current SAMHSA health advisory on methadone:*

- The medication has become more accessible to unauthorized users.
- It can accumulate in potentially harmful doses (especially during the first few days of treatment).
- There has been a rise in Methadone-associated mortality. (SAMHSA, 2004)

(4) *Be familiar with the FDA final policy statement on Methadone that explicitly discusses the topic, "Can Methadone be used for pain control?"*
No separate registration is required to prescribe methadone for treatment of pain. (DEA, 2006)
(5) *Read the new prescribing information for Methadone and the new patient information section.* (Roxane, 2006)
(6) Multiple potential drug-drug interactions can occur with the use of Methadone. A complete list of medications should be obtained prior to prescribing methadone to avoid adverse events, and the patient should be warned to inform any other treating physician that they are taking this medication prior to starting and/or discontinuing medications.
(7) *Pre-use EKG:* There is no current evidence to firmly support the use of an EKG prior to prescribing methadone. Expert opinion includes the use of an EKG for doses of methadone > 100 mg/day or if there are factors that may lead to prolonged QTc interval such as underlying cardiac disease. If the QTc interval is > 500 ms methadone weaning should be considered (Peng, 2008) Others have suggested EKGs in patients over the age of 40 years.

Gabapentin (Neurontin®)
Gabapentin is an anti-epilepsy drug (AEDs - also referred to as anti-convulsants), which has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. See Anti-epilepsy drugs (AEDs) for general guidelines, as well as specific Gabapentin listing for more information and references.

Anti-epilepsy drugs (AEDs) for pain
SPECIFIC ANTI-EPILEPSY DRUGS:
Gabapentin (Neurontin®, Gabarone™, generic available) has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. (Backonia, 2002) (ICSI, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Attal, 2006) This RCT concluded that gabapentin monotherapy appears to be efficacious for the treatment of pain and sleep interference associated with diabetic peripheral neuropathy and exhibits positive effects on mood and quality of life. (Backonia, 1998) It has been given FDA approval for treatment of post-herpetic neuralgia. The number needed to treat (NNT) for overall neuropathic pain is 4. It has a more favorable side-effect profile than Carbamazepine, with a number needed to harm of 2.5. (Wiffen2-Cochrane, 2005) (Zaremba, 2006) Gabapentin in combination with morphine has been studied for treatment of diabetic neuropathy and postherpetic neuralgia. When used in combination the maximum tolerated dosage of both drugs was lower than when each was used as a single agent and better analgesia occurred at lower doses of each. (Gilron-NEJM, 2005) Recommendations involving combination therapy require further study.

Mechanism of action: This medication appears to be effective in reducing abnormal hypersensitivity (allodynia and hyperalgesia), to have anti-anxiety effects, and may be beneficial as a sleep aid. (Arnold, 2007)
Specific pain states:
Acute pain: There is limited evidence to show that this medication is effective for acute pain, and for postoperative pain, where there is fairly good evidence that the use of gabapentin and gabapentin-like compounds results in decreased opioid consumption. This beneficial effect, which may be related to an anti-anxiety effect, is accompanied by increased sedation and dizziness. (Peng, 2007) (Buvanendran, 2007) (Menigaux, 2005) (Pandey, 2005)
Spinal cord injury: Recommended as a trial for chronic neuropathic pain that is associated with this condition. (Lvendoglu, 2004)
CRPS: Recommended as a trial. (Serpell, 2002)
Fibromyalgia: Recommended as a trial. (Arnold, 2007)
Lumbar spinal stenosis: Recommended as a trial, with statistically significant improvement found in walking distance, pain with movement, and sensory deficit found in a pilot study. (Yaksi, 2007)
Side-Effect Profile: Gabapentin has a favorable side-effect profile, few clinically significant drug-drug interactions and is generally well tolerated; however, common side effects include dizziness, somnolence, confusion, ataxia, peripheral edema, and dry mouth. (Eisenberg, 2007) (Attal, 2006) Weight gain is also an adverse effect.
Dosing Information:
Postherpetic neuralgia – Starting regimen of 300 mg once daily on Day 1, then increase to 300 mg twice daily on Day 2; then increase to 300 mg three times daily on Day 3. Dosage may be increased as needed up to a total daily dosage of 1800 mg in three divided doses. Doses above 1800 mg/day have not demonstrated an additional benefit in clinical studies. (Neurontin package insert)
Diabetic neuropathy (off-label indication) – Gabapentin dosages range from 900 mg to 3600 mg in three divided doses (Backonia, 2002) (Eisenber, 2007). Gabapentin is 100% renally excreted.
Recommended Trial Period: One recommendation for an adequate trial with gabapentin is three to eight weeks for titration, then one to two weeks at maximum tolerated dosage. (Dworkin, 2003) The patient should be asked at each visit as to whether there has been a change in pain or function. Current consensus based treatment algorithms for diabetic neuropathy suggest that if inadequate control of pain is found, a switch to another first-line drug is recommended. Combination therapy is only recommended if there is no change with first-line therapy, with the recommended change being at least 30%. (TCA, SNRI or AED). (Jensen, 2006) (Eisenberg, 2007)
Weaning and/or changing to another drug in this class: Gabapentin should not be abruptly discontinued, although this recommendation is made based on seizure therapy. Weaning and/or switching to another drug in this class should be done over the minimum of a week. (Neurontin package insert) *When to switch to pregabalin:* If there is

evidence of inadequate response, intolerance, hypersensitivity or contraindications. There have been no head-to-head comparison trails of the two drugs.

Tramadol (Ultram®)
Tramadol is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic compared to a combination of Hydrocodone/ acetaminophen. (Turturro, 1998) For more information and references, see Opioids for general guidelines, as well as specific Tramadol (Ultram®) listing for more information and references. See also Diabetic neuropathy, Opiods for neurotic pain & Medications for acute pain (analgesics). On 12/30/08 the FDA approved an extended-release once-daily formulation of tramadol (Ryzolt) for the management of moderate to moderately severe chronic pain. Labopharm and marketing partner in the United States, Purdue Pharma, launched the product in 100-mg, 200-mg, and 300-mg dosage strengths in the second quarter of 2009. (FDA, 2008)
Opioids, criteria for use
CRITERIA FOR USE OF OPIOIDS
Therapeutic Trial of Opioids
1) Establish a Treatment Plan. The use of opioids should be part of a treatment plan that is tailored to the patient. Questions to ask prior to starting therapy:
(a) Are there reasonable alternatives to treatment, and have these been tried?
(b) Is the patient likely to improve? Examples: Was there improvement on opioid treatment in the acute and subacute phases? Were there trials of other treatment, including non-opioid medications?
(c) Has the patient received a screen for the risk of addiction? Is there likelihood of abuse or an adverse outcome? See Substance abuse (tolerance, dependence, addition. See Opioids, screening for risk of addiction (Webster, 2008) (Ballvantyne, 2007)
(d) Ask about Red Flags indicating that opioids may not be helpful in the chronic phase: (1) Little or no relief with opioid therapy in the acute and subacute phases. (2) The patient has been given a diagnosis in one of the particular diagnostic categories that have not been shown to have good success with opioid therapy: conversion disorder; somatization disorder; pain disorder associated with psychological factors (such as anxiety or depression, or a previous history of substance abuse). Patients may misuse opioids prescribed for pain to obtain relief from depressed feelings, anxiety, insomnia, or discomforting memories. There are better treatments for this. (Sullivan, 2006) (Sullivan, 2005) (Wilsey, 2008) (Savage, 2008)
(e) When the patient is requesting opioid medications for their pain and inconsistencies are identified in the history, presentation, behaviors or physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision.
2) Steps to Take Before a Therapeutic Trial of Opioids:
(a) Attempt to determine if the pain is nociceptive or neuropathic. Also attempt to determine if there are underlying contributing psychological issues. Neuropathic pain

may require higher doses of opioids, and opioids are not generally recommended as a first-line therapy for some neuropathic pain.
(b) A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics.
(c) Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals.
(d) Baseline pain and functional assessments should be made. Function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale. See Function Measures.
(e) Pain related assessment should include history of pain treatment and effect of pain and function.
(f) Assess the likelihood that the patient could be weaned from opioids if there is no improvement in pain and function.
(g) The patient should have at least one physical and psychosocial assessment by the treating doctor (and a possible second opinion by a specialist) to assess whether a trial of opioids should occur. When subjective complaints do not correlate with imaging studies and/or physical findings and/or when psychosocial issue concerns exist, a second opinion with a pain specialist and a psychological assessment should be obtained. (Sullivan, 2006) (Sullivan, 2005) (Wilsey, 2008) (Savage, 2008) (Ballvantyne, 2007)
(h) The physician and surgeon should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the patient, caregiver or guardian.
(i) A written consent or pain agreement for chronic use is not required but may make it easier for the physician and surgeon to document patient education, the treatment plan, and the informed consent. Patient, guardian, and caregiver attitudes about medicines may influence the patient's use of medications for relief from pain. See Guidelines for Pain Treatment Agreement. This should include the consequences of non-adherence.
(j) Consider the use of a urine drug screen to assess for the use or the presence of illegal drugs.

3) Initiating Therapy

(a) Intermittent pain: Start with a short-acting opioid trying one medication at a time.
(b) Continuous pain: extended-release opioids are recommended. Patients on this modality may require a dose of “rescue” opioids. The need for extra opioid can be a guide to determine the sustained release dose required.
(c) Only change 1 drug at a time.
(d) Prophylactic treatment of constipation should be initiated.
(e) If partial analgesia is not obtained, opioids should be discontinued.

4) On-Going Management. Actions Should Include:

(a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy.
(b) The lowest possible dose should be prescribed to improve pain and function.

(c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. *The 4 A's for Ongoing Monitoring*: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000)
(d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain dairy that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management.
(e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. (Webster, 2008)
(f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion).
(g) Continuing review of overall situation with regard to nonopioid means of pain control.
(h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse. (Sullivan, 2006) (Sullivan, 2005) (Wilsey, 2008) (Savage, 2008) (Ballyantyne, 2007)

5) Recommended Frequency of Visits While in the Trial Phase (first 6 months):
(a) Every 2 weeks for the first 2 to 4 months
(b) Then at approximate 1 ½ to 2-month intervals
Note: According to the California Medical Board Guidelines for Prescribing Controlled Substances for Pain, patients with pain who are managed with controlled substances should be seen monthly, quarterly, or semiannually as required by the standard of care. (California, 1994)

6) When to Discontinue Opioids: See Opioid hyperalgesia. Also see Weaning of Medications. Prior to discontinuing, it should be determined that the patient has not had treatment failure due to causes that can be corrected such as under-dosing or inappropriate dosing schedule. Weaning should occur under direct ongoing medical supervision as a slow taper except for the below mentioned possible indications for immediate discontinuation**.** The patient should not be abandoned.

(a) If there is no overall improvement in function, unless there are extenuating circumstances
(b) Continuing pain with the evidence of intolerable adverse effects; lack of significant benefit (persistent pain and lack of improved function despite high doses of opiates- e.g. > 120 mg/day morphine equivalents)
(c) Decrease in functioning
(d) Resolution of pain
(e) If serious non-adherence is occurring
(f) The patient requests discontinuing
(g) Immediate discontinuation has been suggested for: evidence of illegal activity including diversion, prescription forgery, or stealing; the patient is involved in a motor vehicle accident and/or arrest related to opioids, illicit drugs and/or alcohol; intentional suicide attempt; aggressive or threatening behavior in the clinic. It is suggested that a patient be given a 30-day supply of medications (to facilitate finding other treatment) or be started on a slow weaning schedule if a decision is made by the physician to terminate prescribing of opioids/controlled substances.
(h) Many physicians will allow one “slip” from a medication contract without immediate termination of opioids/controlled substances, with the consequences being a re-discussion of the clinic policy on controlled substances, including the consequences of repeat violations.
(i) If there are repeated violations from the medication contract or any other evidence of abuse, addiction, or possible diversion it has been suggested that a patient show evidence of a consult with a physician that is trained in addiction to assess the ongoing situation and recommend possible detoxification. (Weaver, 2002)
(j) When the patient is requesting opioid medications for their pain and inconsistencies are identified in the history, presentation, behaviors or physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision.

7) When to Continue Opioids

(a) If the patient has returned to work
(b) If the patient has improved functioning and pain
(Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/CoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004)

NSAIDs (non-steroidal anti-inflammatory drugs)
Specific recommendations:
Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional

NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. (Chen, 2008) (Laine, 2008)

Back Pain - Acute low back pain & acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting to negative evidence that NSAIDs are more effective than acetaminophen for acute LBP. (van Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. (Hancock, 2007)

Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another. (Roelofs-Cochrane, 2008) See also Anti-inflammatory medications.

Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in patients with neuropathic pain. (Namaka, 2004) (Gore, 2006)

See NSAIDs, GI symptoms & cardiovascular risk; NSAIDs, hypertension and renal function; & Medications for acute pain; & (analgesics). Besides the above well-documented side effects of NSAIDs, there are other less well-known effects of NSAIDs, and the use of NSAIDs has been shown to possibly delay and hamper healing in all the soft tissues, including muscles, ligaments, tendons, and cartilage. (Maroon, 2006) Revised AGS practice guidelines on the management of persistent pain (including noncancer-related pain) in the elderly recommend that patients avoid NSAIDs and consider the use of low-dose opioid therapy instead, because the risks of NSAIDs in older patients, which include increased cardiovascular risk and gastrointestinal toxicity, usually outweigh the benefits. (AGS, 2009)