

**AccuReview**  
An Independent Review Organization  
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Notice of Independent Review Decision

**DATE OF REVIEW:** November 3, 2011

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**

Prescription Medications

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

This physician is Board Certified in Physical Medicine and Rehabilitation with over 15 years of experience.

**REVIEW OUTCOME:**

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

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

**INFORMATION PROVIDED TO THE IRO FOR REVIEW:**

04-10-08: Office visit, MD  
05-07-08: Office visit, MD  
06-04-08: Office visit,, MD

07-03-08: Office visit, MD  
01-22-09: Office visit, MD  
04-24-09: Office visit, MD  
01-14-11: Evaluation by MD  
01-26-11: Required Medical Examination performed by MD  
02-07-11: Consultation at Imaging DO  
03-07-11: Follow-up evaluation with DO  
04-04-11: Follow-up evaluation with DO  
05-13-11: Follow-up evaluation with DO  
06-13-11: Follow-up evaluation with DO  
07-19-11: Consultation at Diagnostic Imaging with MD  
07-27-11: Follow-up evaluation with MD

### **PATIENT CLINICAL HISTORY [SUMMARY]:**

The claimant sustained trauma to this right shoulder, arm and neck after falling off a ladder on xx/xx/xx. He was been treated for chronic pain secondary to suprascapular neuropathy, impingement syndrome, chronic inflammation of the right shoulder, C5-6 protrusion and cervical disc disruption from C3-7, and myofascial syndrome.

04-10-08: The claimant was evaluated by MD. Dr. reported the following history in his report: A MRI had shown a cyst had formed around the supraspinatus muscle causing impingement of the suprascapular nerve and Dr. diagnosed torn rotator cuff and suprascapular nerve injury with entrapment. Electrophysiologic studies were consistent with (1) severe suprascapular neuropathy; (2) moderately severe carpal tunnel syndrome; (3) ongoing denervation with motor abnormalities in the supraspinatus and infraspinatus. The study did not show any evidence of cervical radiculopathy. Dr. performed 2 surgical procedures: (1) Anterior acromioplasty, exploration of the suprascapular nerve, excision of cyst, and excision of distal clavicle; (2) Carpal tunnel and pronator release. Because of continuing dyesthesias in the distribution of the ulnar nerve in the right forearm and hand and clinical signs of cubital tunnel syndrome plus persistent complaints of pain over the right shoulder in the region of the trapezius extending toward the supraspinatus fossa, Dr. diagnosed ulnar nerve neuritis, persistent painful scapula, and scapularis bursitis and performed a 3<sup>rd</sup> surgery: Transposition of the ulnar nerve and superior pole scapulectomy. The claimant continued to complain of neck pain and headaches and consequently additional diagnostic studies were obtained. A cervical discogram demonstrated abnormal architecture at 4 levels with pain concordance. MRI from 2006 showed: 1. Post-surgical changes from previous acromioplasty. 2. Traumatic/degenerative lesion of the subscapularis tendon. 3. Abnormal signal in the distal portion of the supraspinatus tendon likely reflecting tendinosis. 4. Atrophy of the supraspinatus muscle. Electrophysiologic studies from 2006 were interpreted as consistent with suprascapular neuropathy with ongoing denervation re-innervation to both supraspinatus and infraspinatus muscles with no evidence of cervical radiculopathy. Dr. reported that the claimant's shoulder pain had been effectively controlled with transdermal Fentanyl and breakthrough episodes respond to hydrocodone. He had not required any dose increases and his overall functionality had remained high with a baseline pain rated at 4/10, but increases with

activity as the day progresses. Dr. found on physical examination range of motion of the shoulder was 90 degrees with painful arc for abduction, 90 degree for forward flexion, and that tremulousness occurred at the end points of each movement. There was moderate tenderness of AC joint with downward traction, focal subacromial tenderness, mild painful swelling at insertion of biceps tendon, crepitation during active movements, and atrophy of supraspinatus. Diagnostic Impression: Axis I: pain disorder due to subscapularis neuropathy and impingement syndrome with chronic tendinitis and bursitis; degenerative arthropathy; 4-level cervical disc disruptions and spondylosis; and myofascial pain. Recommendations: Transdermal Fentanyl 25 mcg #15, Hydrocodone 10/325 #: 90, Neurontin 800 mg, Diazepam 10 mg.

05-07-08: The claimant had a follow-up evaluation with MD. Dr. noted he continued to experience chronic pain in the right shoulder with significant limitation in ROM. Pain predictably increases with shoulder activity and is associated with muscle soreness and tightness in his neck and upper back. Increase night time pain was common and not infrequently, interfered with sleep. Recommendations: Decrease transdermal Fentanyl from 25 mcg to 12.5 mcg, Hydrocodone 10/325, Diazepam 10 mg, and Neurontin 800 mg.

06-04-08: The claimant had a follow-up evaluation with MD. Because of chronic inflammation Dr. discussed having an ESI with Dr.. Recommendations: Continue same medications.

07-03-08: The claimant had a follow-up evaluation with MD. It was noted that the decrease in transdermal Fentanyl from 25 mcg to 12.5 mcg resulted in an increase in his baseline pain from 4/10 to 6/10 and his ability to remain active declined and he had more frequent episodes of breakthrough pain during activity. It was also noted that previous requests for steroid injections had been denied, so the claimant would pay for an injection himself. His transdermal Fentanyl was increased back up to 25 mcg.

01-22-09: The claimant had a follow-up evaluation with MD. It was noted that at his own expense, the claimant had been using Amrix, a once a day skeletal muscle relaxant that he takes approximately 5 hours before his bedtime.

04-24-09: The claimant had a follow-up evaluation with MD. It was reported that he had an increase in pain in his neck and upper back following his involvement in an MVA in late when he was rear-ended. He was evaluated in the ER and x-rays were taken of his right and left shoulders, right hand, and lumbar and cervical spine. There was no evidence of acute injury, but there was evidence of chronic changes. On physical examination there was mild tenderness to palpation over the cervical spine and in the suboccipital muscles, tightness in the trapezius with diffuse painful trigger points bilaterally, and no evidence of cervical root irritation. Biceps, triceps, and brachioradialis reflexes were 1+ and symmetrical. Axial compression=pressure sensation only. Spurling's and Lhermitte's tests were negative for radicular pain. There was also pain over the suprascapular notch and under superomedial angle of the scapula; pain and

apprehension on Anterior Drawer test; moderate tenderness of AC joint; focal subacromial tenderness; crepitation with attempted circumduction; and atrophy of supraspinatus. There was positive impingement sign and speed test for biceps tendinitis. Recommendations: Transdermal Fentanyl 25 mcg, Hydrocodone 10/325, Neurontin 800 mg, and Diazepam 10 mg.

01-14-11: The claimant was evaluated by, MD to assess his future functional potential with an Interdisciplinary evaluation and schedule a Medication Management Consultation with MD. It was noted that MD had lost his license and the claimant was devoid of long-term opioids over the past two months. It was reported that he had current complaints of postoperative neck pain radiating to both hands, low back pain radiating to both feet, and independent right shoulder pain. He complained of weakness, numbness and tingling in all four extremities and denying long tract signs. His pain is extreme (9/10) with the pain made worse by all acuities and better by rest. On physical examination he had tenderness mainly in his trapezii and paravertebral muscles from C5-T2 in the neck. He had minimal motion showing only 15 degrees rotation in both directions and 5 degrees of lateral bend with only negligible sagittal motion. He brings his shoulders up only to 90 degrees due to neck pain, but has no specific localizing neurologic findings. In the lumbar spine he demonstrated segmental rigidity at L4-S1 with only 10 degrees of lateral bend and sagittal motion of only 30 degrees. Restricted SLR only to 45 degrees bilaterally with back pain primarily and no localizing neurologic findings. Diagnostic impression: 1. Chronic early postoperative cervical radicular pain with current physical exam findings of extreme mobility deficits and muscle guarding without current evidence of active radiculopathy and recent ACDF at C4/5. 2. Chronic bilateral lumbar radicular pain with current findings of severe muscle guarding and mobility deficits with L4-S1 segmental rigidity. 3. Chronic postoperative right shoulder pain with current findings of severe mobility deficits. 4. [Non-compensable deconditioning syndrome]. 5. [Non-compensable chronic pain syndrome with medical/psychological features including mental stress with psychophysiological symptoms, depressive symptoms (severe), chronic deficits of functioning, abnormal mental stress, prescription medication issues (Fentanyl/Hydrocodone), inhibition of physical function, extended period of disability (20 years TTD), financial stressors, other disability payments. Recommendations: To undergo an interdisciplinary evaluation with a PT/Disability assessment and an FCE covering the affected compensable body parts with an MHE. If the claimant is just interested primarily in medication, a Medication Management Consultation with MD will be set up.

01-26-11: A Required Medical Examination was performed by MD. Dr rendered the following opinions: 1. The patient is currently without a treating doctor as described to me by him today. Treatment that was rendered up until October 2010 appears to be outside of the ODG. He did suffer traumatic injuries to this right upper extremity and cervical area, which was surgically corrected. Ongoing treatment 19 years post such trauma appears not to be specifically related to the injuries in question and the surgeries performed. Degree of chronic pain and reliance on opioids appears to have generated the continued need for ongoing care. 2. Based on the records and his stated

comments, no documentation supporting improvement with medications. He continued to complain of pain and continued to receive prescription medications. 3. No further diagnostic tests appear to be indicated. This patient came off all of his medication without any weaning or tapering and is now outside of the timeframes, which would ordinarily be construed as withdrawal potential problems. Therefore, ongoing treatment at this stage should base on ODG criteria, follow a different approach to that what was rendered up until the end of last year. 4. Fentanyl patches: At this late stage, the use of the patches and the level of pain control appear to exceed the requirements. Furthermore, there is no documentation that indicates that there had been an improvement resulting from the use of the substance and this has not enable him to return to gainful employment or increased activities of daily living per the documentation provided. Hydrocodone 10 mg t.i.d.; for breakthrough pain: The patient informs me that in fact he may have been receiving 120 per month, of which 90 were utilized for the work injury and 30 were for other issues. This is not verifiable per the medical records. However, the use of hydrocodone at this late stage also is questionable. Neurontin for paresthesia: This was being used off label. The ODG supports the use thereof if there is a documented reason and this ordinarily would comprise neuropathic type pain. This patient had posttraumatic carpal tunnel, ulnar nerve entrapment at the elbow, and right shoulder repair surgery, and considering the timeframes, the continued use of this substance also does not appear to be within the ODG criteria. Diazepam 10 mg: The patient has been on that for muscle spasms and it is a benzodiazepine, which is not recommended per the ODG for long-term use mainly due to its dependence and addictive properties. Amrix 15 mg: This is a cyclobenzaprine in a long-acting form and once again, the ODG does not support the use of muscle relaxants long term.

02-07-11: The claimant had a consultation evaluation at Diagnostic Imaging with DO. Dr. noted he continued with chronic neck and arm pain and was allergic to aspirin. On physical examination there was cervical dorsal paravertebral muscle spasm and tenderness. Range of motion of the shoulders was normal. No crepitus was appreciated. Range of motion of the cervical spine was markedly reduced, especially on right and left side bending and to a lesser degree on right and left rotation. Deep tendon reflexes were 2+/2+ bilaterally. Motor strength and sensation were bilaterally symmetrical and appropriate. Clinical impression: Post-laminectomy syndrome cervical spine and chronic neck pain requiring narcotic analgesia. Dr. explained to Mr. that was not a chronic pain center and he could prescribe his analgesics for a month or two, he would need to be transferred to a chronic pain center where more therapeutic modalities were available. Dr. renewed his medications including Duragesic, Norco, Neurontin, and Diazepam.

03-07-11: The claimant had a follow-up evaluation with, DO. It was noted that after getting back on his full panoply of analgesic medication he feels better and is significantly more functional in his daily activities. Dr. was trying to transfer his care to a chronic pain center at Hospital.

04-04-11: The claimant had a follow-up evaluation with, DO. It was noted the chronic pain program does not accept Worker's Comp insurance so his care would be transferred to Chronic Pain Center. He was given a one month medication refill.

05-13-11: The claimant had a follow-up evaluation with DO. It was noted the claimant had an extremely unsatisfactory experience at Chronic Pain Clinic. Dr. maintained his medications for a month or so until transferred care could be arranged.

06-13-11: The claimant had a follow-up evaluation with DO. It was noted that the addition of Duragesic transcutaneous patches to his regimen had been successful as it significantly improved the quality of his pain relief. His prescriptions were refilled and he was referred to Dr., a pain management physician.

07-19-11: The claimant had a consultation evaluation at Diagnostic Imaging with MD. On physical examination Dr. found 2-3+ SGT over the cervical spine and thus Spurling's and Lhermitte's were difficult to assess secondary to his guarding. Tenderness over bilateral cervical facets C3 through T1 and a TOS was equivocally positive bilaterally with fourth and fifth finger numbness with elevation. On neurologic evaluation he had hypoactive reflexes of the upper extremities. Motor was grossly intact except give away weakness bilaterally of grip. Pin sensation was equivocally intact with distraction. Clinical impression: Cervical post-laminectomy pain syndrome, cervical disc disease, cervical radiculopathy, peripheral neuropathy, chronic pain syndrome, anxiety, and low back pain, which he is not sure of the compensability of. Recommendations: A series of cervical epidural steroid injections with epidurogram, possibly facet injections. Also the possibility of a spinal cord stimulator. Dr. recommended continuing medications including Fentanyl 25 mcg q48h, Hydrocodone 10/325 4 per 24 hours breakthrough pain, Diazepam 10 mg 2 per 24 hours, and Neurontin 800 mg, i.e. 2400 mg daily.

07-27-11: The claimant had a follow-up evaluation with MD. It was noted workers comp was currently not covering his medications and he was angry at Dr. for taking him off his med. Dr. prescribed Clonidine, 0.1 mg and recommended the claimant speak with his adjuster and possibly get an IRO.

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

Denial of prescription medications is partially overturned. Per ODG pain chapter: long acting opioids (in this case Fentanyl) are recommended to stabilize medication levels, and short acting opioids (in this case Hydrocodone) are recommended for moderate to severe break through pain. Fentanyl is not recommended for use in routine musculoskeletal pain due to significant side effects. In this case, pain is more than routine; it is chronic and of multiple etiologies. ODG criteria for use of opioids, when to continue opioids 7)a) if the patient returned to work and/or b) if the patient has improved functioning and pain. Review of submitted clinicals reveal that the claimant is more functional on a stable medication regimen that is frequently monitored by monthly physician office visits to assess actual use, effectiveness, adverse side effects and aberrant behavior.

ODG pain chapter recommends Neurontin for neuropathic pain. In this case medical records document cervical radiculopathy and suprascapular and ulnar compressive neuropathies.

ODG pain chapter does not recommend Diazepam for long term use because long term efficiency is unproven and risk of psychological and physical dependence or frank addiction.

Therefore, in summary: Partial agreement of prescription of Fentanyl, Hydrocodone and Neurontin and therefore the denial of these prescriptions are overturned, but disagreement with the prescription of Diazepam, therefore the denial of Diazepam is upheld.

ODG:

## **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 \(tolerance, dependence, addiction\)](#). See [Opioids, screening for risk of addiction](#). ([Webster, 2008](#)) ([Ballyantyne, 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](#)) ([Ballyantyne, 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 diary 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  
[\(Washington, 2002\)](#) [\(Colorado, 2002\)](#) [\(Ontario, 2000\)](#) [\(VA/DoD, 2003\)](#) [\(Maddox-AAPM/APS, 1997\)](#) [\(Wisconsin, 2004\)](#) [\(Warfield, 2004\)](#)

<p>Opioids for chronic pain</p>	<p><i>Recommendations for general conditions:</i></p> <ul style="list-style-type: none"> <li>- <i>Neuropathic pain:</i> Opioids have been suggested for neuropathic pain that has not responded to first-line recommendations (<a href="#">antidepressants</a>, <a href="#">anticonvulsants</a>). There are no trials of long-term use. There are virtually no studies of opioids for treatment of chronic lumbar root pain with resultant neuropathy. See <a href="#">Opioids for neuropathic pain</a>.</li> <li>- <i>Chronic back pain:</i> Appears to be efficacious but limited for short-term pain relief. Long-term efficacy is unclear (&gt;16 weeks), and there is also limited evidence for the use of opioids for chronic low back pain. (<a href="#">Martell-Annals, 2007</a>) Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. There is no evidence to recommend one opioid over another. In patients taking opioids for back pain, the prevalence of lifetime substance use disorders has ranged from 36% to 56% (a statistic limited by poor study design). Limited information indicated that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior. (<a href="#">Martell-Annals, 2007</a>) (<a href="#">Chou, 2007</a>) There are three studies comparing Tramadol to placebo that have reported pain relief, but this increase did not necessarily improve function. (<a href="#">Deshpande, 2007</a>)</li> <li>- <i>Headaches:</i> not recommended, in particular, due to the risk of medication overuse headache. (<a href="#">Lake, 2008</a>) (<a href="#">Olesen, 2006</a>) See <a href="#">Medication overuse headache</a>.</li> <li>- <i>Osteoarthritis:</i> Not recommended as a first-line therapy. Recommended on a trial basis for short-term use after there has been evidence of failure of first-line medication options such as acetaminophen or NSAIDs when there is evidence of moderate to severe pain. Also recommended for a trial if there is evidence of contraindications for use of first-line medications. Under study for long-term use as there is a lack of evidence to allow for a treatment recommendation. If used on a long-term basis, the criteria for use of opioids should be followed. See <a href="#">Opioids for osteoarthritis</a> for citations.</li> <li>- <i>Nociceptive pain:</i> Recommended as the standard of care for treatment of moderate or severe nociceptive pain (defined as pain that is presumed to be maintained by continual injury, with the most common example being pain secondary to cancer).</li> <li>- <i>Mechanical and compressive etiologies:</i> rarely beneficial.</li> </ul> <p>Chronic pain can have a mixed physiologic etiology of both neuropathic and nociceptive components. In most cases, <b>analgesic</b> treatment should begin with acetaminophen, aspirin, and NSAIDs (as suggested by the WHO step-wise algorithm). When these drugs do not satisfactorily reduce pain, opioids for moderate to moderately severe pain may be added to</p>
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(not substituted for) the less efficacious drugs. A major concern about the use of opioids for chronic pain is that most randomized controlled trials have been limited to a short-term period ( $\leq 70$  days). This leads to a concern about confounding issues such as tolerance, opioid-induced hyperalgesia, long-range adverse effects such as hypogonadism and/or opioid abuse, and the influence of placebo as a variable for treatment effect. (Ballantyne, 2006) (Furlan, 2006) Long-term, observational studies have found that treatment with opioids tends to provide improvement in function and minimal risk of addiction, but many of these studies include a high dropout rate (56% in a 2004 meta-analysis). (Kalso, 2004) There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain. (Martell-Annals, 2007) Current studies suggest that the “upper limit of normal” for opioids prior to evaluation with a pain specialist for the need for possible continuation of treatment, escalation of dose, or possible weaning, is in a range from 120-180 mg morphine equivalents a day. (Ballantyne, 2006) (AMDG, 2007)

There are several proposed guidelines for the use of opioids for chronic non-malignant pain, but these have not been evaluated in clinical practice, and selection of the patient that will best respond to this treatment modality remains difficult. (Nicholas, 2006) (Stein, 2000) One of the most recent of these guidelines is the Agency Medical Director’s Group (AMDG) Guidelines from Washington State. This guideline includes an opioid dosing calculator. (AMDG, 2007)

*Outcomes measures:* It is now suggested that rather than simply focus on pain severity, improvements in a wide range of outcomes should be evaluated, including measures of functioning, appropriate medication use, and side effects. Measures of pain assessment that allow for evaluation of the efficacy of opioids and whether their use should be maintained include the following: 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. (Nicholas, 2006) (Ballantyne, 2006) A recent epidemiologic study found that opioid treatment for chronic non-malignant pain did not seem to fulfill any of key outcome goals including pain relief, improved quality of life, and/or improved functional capacity. (Eriksen, 2006)

*Tolerance and addiction:* Opioid tolerance develops with the repeated use of opioids and brings about the need to increase the dose and may lead to sensitization. It is now clear that analgesia may not occur with open-ended escalation of opioids. It has also become apparent that analgesia is not always sustained over time, and that pain may be improved with weaning of opioids. (Ballantyne, 2006) (Ballantyne, 2003) See [Substance abuse \(tolerance, dependence, addiction\)](#).

*Behavior reinforcement:* A major concern in the use of opioids has been that a focus on this treatment without coordination with other modalities, such as [psychosocial or behavioral therapy](#), may simply reinforce pain-related behavior, ultimately undermining rehabilitation that has been targeted at functional restoration. (Ontario, 2000) It has been shown that pain behavior can be reinforced by the prescribing of opioids, generally on an unintentional basis by the patient. (Fordyce, 1991)

*Overall treatment suggestions:* Current guidelines suggest the following:

- A trial of opioids as a first step in treatment, and the steps involved are outlined in the [Criteria for Use of Opioids](#). The trial includes an initiation phase that involves selection of the opioid and initial dose. (VA/DoD, 2003)
- There is then a titration phase that includes dose adjustment. At this phase it may be determined that opioids are not achieving the desired outcomes, and they should be discontinued.
- The final stage is the maintenance phase. If pain worsens during this phase the differential to evaluate includes disease progression, increased activity, and/or new or increased pre-existing psychosocial factors that influence pain. In addition, the patient may develop hyperalgesia, tolerance, dependence or actual addiction. (Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004) See [Substance abuse \(tolerance, dependence, addiction\)](#). See also [Implantable pumps for narcotics](#). See also Opioids in the

	<a href="#">Low Back Chapter</a> . See <a href="#">Criteria for Use of Opioids</a> .
Opioids for neuropathic pain	<p>Not recommended as a first-line therapy. Opioid analgesics and Tramadol have been suggested as a second-line treatment (alone or in combination with first-line drugs). A recent consensus guideline stated that opioids could be considered first-line therapy for the following circumstances: (1) prompt pain relief while titrating a first-line drug; (2) treatment of episodic exacerbations of severe pain; (3) treatment of acute neuropathic pain; &amp; (4) treatment of neuropathic cancer pain. (<a href="#">Dworkin, 2007</a>) Response of neuropathic pain to drugs may differ according to the etiology of therapeutic pain. There is limited assessment of effectiveness of opioids for neuropathic pain, with short-term studies showing contradictory results and intermediate studies (8-70 days) demonstrating efficacy. (<a href="#">Eisenberg-Cochrane, 2006</a>) (<a href="#">Eisenberg-JAMA, 2005</a>) The results of short-term trials were mixed with respect to analgesia (less than 24 hours of treatment). Intermediate trials (average treatment duration of 28 days) showed statistical significance for reducing neuropathic pain by 20% to 30% (and 30% may be the threshold for describing a meaningful reduction of pain).</p> <p><i>Treatment of chronic lumbar root pain:</i> A limitation of current studies is that there are virtually no repeated dose analgesic trials for neuropathy secondary to lumbar radiculopathy. A recent study that addressed this problem found that chronic lumbar radicular pain did not respond to either a tricyclic antidepressant or opioid in doses that have been effective for painful diabetic neuropathy or postherpetic neuralgia. Morphine was the least effective treatment (reducing leg and back pain by 1-7% compared to placebo). Sample size and drop out rate was a limitation. (<a href="#">Khoromi, 2007</a>)</p> <p><i>Consideration of risks and side effects:</i> Opioids are considered a second-line treatment for several reasons: (1) head-to-head comparisons have found that opioids produce more side effects than TCAs and gabapentin; (2) long-term safety has not been systematically studied; (3) long-term use may result in immunological and endocrine problems (including hypogonadism); (4) treatment may be associated with hyperalgesia; &amp; (5) opioid use is associated with misuse/abuse. Opioids may be a safer choice for patients with cardiac and renal disease than antidepressants or anticonvulsants. (<a href="#">Namaka, 2004</a>)</p> <p><i>Specific drugs:</i> Morphine: superior to placebo in post-herpetic neuralgia, phantom limb and painful diabetic neuropathy (<a href="#">number needed to treat</a> of 2.5). Oxycodone: post-herpetic neuralgia and painful diabetic neuropathy (NNT of 2.6). Tramadol: 2 trials of painful polyneuropathy and a trial of post-herpetic neuropathy (overall NNT of 3.9). Other disease states that have been studied include post-amputation pain. (<a href="#">Finnerup, 2005</a>) (<a href="#">Finnerup, 2007</a>) (<a href="#">Wu, 2008</a>)</p>

## CRITERIA FOR USE OF OPIOIDS

### Long-term Users of Opioids (6-months or more)

#### 1) Re-assess

- (a) Has the diagnosis changed?
- (b) What other medications is the patient taking? Are they effective, producing side effects?
- (c) What treatments have been attempted since the use of opioids? Have they been effective? For how long?
- (d) Document pain and [functional improvement](#) and compare to baseline. 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. Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument.
- (e) Document adverse effects: constipation, nausea, vomiting, headache, dyspepsia, pruritis, dizziness, fatigue, dry mouth, sweating, hyperalgesia, sexual dysfunction, and sedation.
- (f) Does the patient appear to need a psychological consultation? Issues to examine would include motivation, attitude about pain/work, return-to-work, social life including interpersonal and work-related relationships.
- (g) Is there indication for a screening instrument for abuse/addiction. See Substance Abuse Screening.

#### 2) Strategy for maintenance

- (a) Do not attempt to lower the dose if it is working

(b) Supplemental doses of break-through medication may be required for incidental pain, end-of dose pain, and pain that occurs with predictable situations. This can be determined by information that the patient provides from a pain diary or evaluation of additional need for supplemental medication.

(c) The standard increase in dose is 25 to 50% for mild pain and 50 to 100% for severe pain (Wisconsin)

### 3) Visit Frequency

(a) There is no set visit frequency. This should be adjusted to the patient's need for evaluation of adverse effects, pain status, and appropriate use of medication, with recommended duration between visits from 1 to 6 months.

NSAIDs (non-steroidal anti-inflammatory drugs)	<p>Specific recommendations:</p> <p><i>Osteoarthritis (including knee and hip):</i> 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. (<a href="#">Chen, 2008</a>) (<a href="#">Laine, 2008</a>)</p> <p><i>Back Pain - Acute low back pain &amp; acute exacerbations of chronic pain:</i> 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. (<a href="#">van Tulder, 2006</a>) (<a href="#">Hancock, 2007</a>) 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. (<a href="#">Roelofs-Cochrane, 2008</a>) 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. (<a href="#">Hancock, 2007</a>)</p> <p><i>Back Pain - Chronic low back pain:</i> 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. (<a href="#">Roelofs-Cochrane, 2008</a>) See also <a href="#">Anti-inflammatory medications</a>.</p> <p><i>Neuropathic pain:</i> 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. (<a href="#">Namaka, 2004</a>) (<a href="#">Gore, 2006</a>)</p> <p>See <a href="#">NSAIDs, GI symptoms &amp; cardiovascular risk</a>; <a href="#">NSAIDs, hypertension and renal function</a>; &amp; <a href="#">Medications for acute pain</a> (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. (<a href="#">Maroon, 2006</a>) 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. (<a href="#">AGS, 2009</a>)</p>
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<b>Benzodiazepines</b>	<p>Not recommended for long-term use because long-term efficacy is unproven and there is a risk of psychological and physical dependence or frank addiction. Most guidelines limit use to 4 weeks. Benzodiazepines are a major cause of overdose, particularly as they act synergistically with other drugs such as opioids (mixed overdoses are often a cause of fatalities). Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly (3-14 day). Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. Tolerance to lethal effects does not occur and a maintenance dose may approach a lethal dose as the therapeutic index increases. The best prevention for substance use disorders due to benzodiazepines is careful prescribing. (<a href="#">Baillargeon, 2003</a>) (<a href="#">Ashton, 2005</a>) (<a href="#">Dickinson, 2009</a>) (<a href="#">Lader, 2009</a>)</p> <p>See also <a href="#">Anxiety medications in chronic pain</a>; &amp; <a href="#">Insomnia treatment</a>. Benzodiazepines that are commonly prescribed include the following: <a href="#">alprazolam</a>, <a href="#">chlordiazepoxide</a>, <a href="#">clonazepam</a>, <a href="#">clorazepate</a>, <a href="#">diazepam</a>, <a href="#">estazolam</a>, <a href="#">flurazepam</a>, <a href="#">lorazepam</a>, <a href="#">midazolam</a>, <a href="#">oxazepam</a>, <a href="#">quazepam</a>, <a href="#">temazepam</a>, &amp; <a href="#">triazolam</a>. (<a href="#">Clinical Pharmacology, 2010</a>)</p>
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**A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:**

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**
- INTERQUAL CRITERIA**
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**
- MILLIMAN CARE GUIDELINES**
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**
- TEXAS TACADA GUIDELINES**
- TMF SCREENING CRITERIA MANUAL**
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**