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NOTICE OF INDEPENDENT REVIEW DECISION

DATE OF REVIEW:

June 30, 2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Prescription drugs: Norco, Lunesta, Cymbalta and OxyContin

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

M.D., Board Certified Orthopedic Surgeon

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)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

OD Guidelines

Office notes, Dr., 07/12/04

Chiro notes, Dr., 07/13/04, 07/14/04, 07/15/04, 07/19/04, 07/20/04, 07/21/04, 07/22/04, 07/27/04, 07/28/04, 07/29/04, 08/02/04, 08/03/04, 08/04/04, 08/05/04, 09/20/04, 09/21/04, 09/22/04, 10/11/04, 10/12/04, 10/13/04, 10/14/04, 11/09/04, 11/11/04, 11/16/04, 11/17/04, 12/13/04, 12/14/04, 12/15/04, 12/16/04

Office notes, Dr., 07/29/04, 08/12/04, 08/26/04, 09/16/04, 10/19/04, 11/16/04, 12/15/04

MRI cervical spine, 09/09/04

MRI lumbar spine, 11/05/04

RME, Dr., 10/14/04

Procedure note, 10/19/04

Phone consult, Dr., 11/03/04

MRI thoracic spine, 11/05/04

Note from Dr.

Prescription Report, 03/24/10

Injections, 12/06/04

Prescription, Dr., 12/15/04, 01/12/05

Procedure note, 12/20/04

Office note, Dr., 12/28/04

ER report, 03/10/05

Office notes, Dr., 06/16/05, 07/21/05, 08/04/05, 08/18/05, 10/13/05, 11/10/05, 12/08/05, 02/23/06, 07/20/06, 12/21/06, 07/16/07, 08/16/07

PT note, 08/03/05

Prescription, 08/18/05

Operative Report, 08/25/05

PT graph, 09/06 – 10/11/05

Work restrictions, 10/13/05

Functional abilities evaluation, 02/07/06

Office note, Dr., 03/03/06
RME, Dr., 03/27/06, 01/26/07
Office notes, Dr., 05/25/06, 09/12/06, 03/24/10, 04/21/10
Office notes, Dr., 08/17/06, 10/12/06, 11/07/06, 12/07/06, 03/01/07, 03/29/07, 05/01/07
MMI and IR determination, Dr., 11/09/06
FCE, 11/09/06
Reviewed records, Dr., 11/16/07
Prescription, 03/24/10, 04/21/10
Review, Dr., 04/01/10
Patient Receipt, 04/21/10
Review, Dr., 04/28/10
Sedgwick CMS 4/1/10, 4/28/10

PATIENT CLINICAL HISTORY SUMMARY

The claimant is a male who sustained injuries to the head, cervical spine, upper back and lumbar spine on xx/xx/xx when a jammed bundler's 2 mechanical arms catapulted him while bending over the machine into the wall behind him. He reportedly was seen initially and given prescription medications and returned to work, but his symptoms continued to escalate. On 07/11/04 he had x-rays and a CT. These reports were not provided. He started treating with chiropractor. Dr. saw the claimant on 07/29/04 for complaints of persistent pain across the neck and shoulders and severe pain between the shoulder blades and frequent numbness in both arms, greater on the left from the left elbow and forearm and into the fourth and fifth digits. He also had stiffness in the low back and some intermittent burning pain into both hips. It was unclear if it was true radicular pain. He was taking Naprosyn, Lortab and Zanaflex. The examination showed marked paraspinous and periscapular spasms, moderate tenderness and distal paresthesias with palpation greater on the left. Acute cervical strain, possible cervical disc injury and acute thoracic strain were diagnosed. A cervical MRI, hold Naprosyn, a trial of Celebrex and Valium and continuation of Lortab were recommended. At the 08/12/04 followup he had ongoing neck pain radiating into both arms, greater on the left and increasing back pain radiating down both legs laterally. He was also very anxious and depressed and was not sleeping well. He had some relief with Valium. He had marked suprascapular and periscapular tenderness and guarded movement. Acute lumbar strain and possible lumbar disc injury were diagnosed. Continuation of Celebrex, consider cortisone after EMG, a trial of Soma, increase Norco and a trial of Restoril were recommended.

A cervical MRI on 09/09/04 revealed a mild annular disk bulging at C3-4 level not associated with significant central stenosis or foraminal effacement. There was a somewhat more prominent, approximately 3 millimeter, posterior and lateral disk bulging at C4-5 produced mild effacement of the thecal sac, lateral recesses and proximal exit foramina. There was no significant central stenosis. The degree of proximal effacement was mild. There was mild annular disk bulging C5-6 without central stenosis or foraminal effacement. Dr. re-evaluated the claimant on 09/16/04 for thoracic, neck and low back pain, severe thoracic burning, less severe neck pain and arm pain, but ongoing upper extremity paresthesias. Recent EMG studies were reportedly positive for bilateral carpal tunnel syndrome, greater on the right and C7 radicular left moderate-severe. He was unable to sleep. He had a trial of Kadian with good pain relief, but itching. He was anxious, had left suprascapular tenderness and bilateral periscapular tenderness greater on the left. Thoracic pain, probable soft tissue injury and bilateral periscapular tenderness greater on the left were diagnosed. Surfak, discontinue Kadian, a trial of OxyContin, increase Gabitril and continue Norco, Celebrex and Soma were recommended. A lumbar MRI on 11/05/04 revealed mild loss of disc space height and disc desiccation at T8-9, T9-10, T10-11. At T8-9 and T9-10 there were small posterior disc osteophyte complexes effacing the ventral thecal sac. However, there was no cord compression or significant central canal stenosis at either level.

There was no evidence of a thoracic compression fracture. There was also no significant central canal stenosis at any level. Dr. performed a required medical evaluation on 10/14/04

and indicated that a CT of the head was normal, thoracic plain films showed early degenerative changes, lumbosacral plain films showed mild dextroscoliosis and early anterior degenerative changes and cervical x-rays were normal. The dates and reports of such were not provided. He was taking Soma, Celebrex, Dizaepam, Ambien, Hydrocodone, OxyContin and Gabitril. The examination showed myofascial tenderness throughout the upper and mid trapezius, levator scapula, splenius capitis and rhomboid region, full sensation C2-T1 with the exception down the left, evident light touch alteration (though not complete loss) in the C6 distribution – less present on the right, some alteration of sensation in the thenar eminence, decreased left brachioradialis relative to the right brachioradialis, alteration sensation in the right C7 dermatomal distribution that does not radiate ventrally past mid axillary line and myofascial tenderness in this region. Dr. opined that the most reasonable medications would include simple anti-inflammatory agents, single muscle relaxant (currently is on two highly active muscle relaxants), neuropathic pain agent such as Gabitril or Neurontin, and potentially opioid only until the claimant could undergo cervical epidural steroid injections. On 10/19/04 trigger point injections were given in the fan pattern at the point of greatest tenderness at the superior medial border of the right scapula. Dr. talked with the claimant on 11/03/04 reporting inadequate pain relief and significant anxiety/depression issues. Discontinuation of Valium and start Wellbutrin were advised.

A thoracic MRI on 11/05/04 revealed mild loss of disc space height and disc desiccation at T8-9, T9-10, T10-11. At T8-9 and T9-10 there were small posterior disc osteophyte complexes effacing the ventral thecal sac. However, there was no cord compression or significant central canal stenosis at either level. There was no evidence of a thoracic compression fracture. The claimant continued chiropractic treatments.

The claimant continued treating with Dr. through 12/15/04 who referred him to Dr.. On 12/20/04 cervical epidural steroid injection and trigger point injections were administered with improvement. A discogram was recommended. He presented to the emergency room on 03/10/05 for pain and swelling in the left knee for three days. A left knee strain was diagnosed and a knee immobilizer, crutches, ice and followup with an orthopedic surgeon were advised. Dr. saw the claimant on 06/16/05 for chronic intractable back pain, radicular symptoms and left knee pain status post anterior cruciate ligament repair and radicular symptoms down the back and into the right leg. Mild thoracic trigger points were noted and the examination was noted to be “unchanged” from 06/09/05. Lumbar radiculopathy in the right L5 pattern with weakness of the extensor hallucis longus, myofascial pain syndrome, history of cervical radiculopathy and thoracic sprain/strain were diagnosed. Bilateral carpal injections were given and lumbar epidural steroid injection and continuation of pain medications were advised. On 08/25/05 a right transforaminal epidural steroid injection with selective nerve root block was given without real improvement. He continued treating with Dr. through 02/23/06 and was advised to see Dr. regarding possible spinal surgery. Dr. saw the claimant on 03/27/06 for low back and right leg pain. A posterior lumbar interbody fusion L2-3 and L3-4 was recommended, but was not done.

Dr. performed a required medical evaluation on 03/27/06 for mid thoracic pain equal to mid low back pain, intermittent right posterolateral thigh, calf and foot pain with numbness, intermittent right upper extremity pain and numbness into the ulnar aspect of the hand and minor bowel and bladder dysfunction. He was noted to have had 3 cervical injections with good, but temporary relief and 1 lumbar injection with limited temporary relief. His medications included Celebrex, Protonix, Ambien, Wellbutrin, Alprazolam, Hydrocodone and OxyContin.

The examination showed kneeling to the right knee somewhat slowly, moved off and on the exam table with minimal difficulty, significant pain with passive movement of the low back, aggravation of low back symptoms with light pressure of the apex of the head, supine straight leg raise on the left at 20 degrees and on the right at 10 degrees caused significant discomfort. He had an absent left infrapatellar reflex, apparently due to previous left anterior cruciate ligament stretch. Spondylogenic cervicothoracic spine pain with right upper extremity symptoms chronic anatomic etiology undetermined, spondylogenic lumbosacral spine pain with right lower extremity symptoms chronic of undetermined etiology were

diagnosed. Dr. recommended weaning from narcotic pain medications to appropriate non-narcotic pain medications.

The claimant sought a second opinion with Dr. on 05/25/06 regarding back surgery. He was also seeing Dr., psychiatrist for adjustment disorder, depression and anger outburst. He reported radiating pain down the right lower extremity down the posterior thigh and occasionally into the foot with numbness. He denied bowel or bladder incontinence. Motion was restricted, there was altered numbness again in the lower extremity seemed located in the lateral distal thigh and leg and grade 0/4 right ankle reflexes. There was also soreness and pain with hamstring stretching. Low back pain with radiation with lower extremity numbness and discogenic back pain were diagnosed. Seroquel was prescribed. He continued treating with Dr., and Dr.. On 11/09/06 Dr. determined the claimant to be at maximum medical improvement as of 06/26/06 and assigned a 10 percent whole person impairment rating. A functional capacity evaluation on 11/09/06 noted the claimant's function indeterminate which did not meet his self reported light-medium level of work demand, but felt that he should be considered at least capable of sedentary level of demand. On 12/21/06 Dr. assigned a 19 percent whole person impairment rating. Dr. re-evaluated the claimant again on 01/26/07 for a required medical evaluation. The examination showed a slow, but normal gait, he said he was unable to pick up an object from the floor. He moved onto and off the exam table with minimal difficulty. Light touch over the right lower extremity caused significant pain. Any passive movement of the low back including minimal rotation of the trunk and torso caused significant light pressure over the apex of the head significantly aggravated low back symptoms. He had minimal forward lumbar and pelvic flex, mild limitation of active extension and active lateral lumbar flexion bilaterally. Supine straight leg raise at 10 caused significant pain bilaterally. He had absent left infrapatellar reflex apparently due to previous left anterior cruciate ligament reconstruction. Multiple non-physiologic findings were diagnosed. He recommended weaning from use of narcotic pain meds over 6-12 weeks. He felt appropriate medications for the treatment of such symptoms would consist of a provision of an oral anti-inflammatory such as Celebrex, muscle relaxer such as methocarbamol, non-narcotic pain medication such as Tramadol and may require use of such meds on an indefinite basis. The claimant continued treating with Allan Walling and Dr. through 08/16/07.

Dr. reviewed records on 11/16/07 and stated the claimant was currently taking Lyrica, Celexa, Norco, Flexeril, Prevacid, Xanax, Celebrex and OxyContin. He did not feel the current meds were consistent with typical treatment plan in that his symptoms at worst appeared to be mechanical origin with limited physical and imaging findings and obvious discrepancy between this and the magnitude of subjective complaints. He appeared to have virtually no symptomatic or functional improvement from these meds and continued use of such meds, given inconstant with basic tenants of pain management and was inconsistent with ODG. He said he would have never started the claimant on such a regime of medications and saw no basis for continuation of the vast majority of these meds and should be weaned from all of them other than Celebrex, Prevacid and Flexeril. He said these meds would be most appropriate for treating chronic mechanical pain which he may have and that there was absolutely no indication for continued provision of other meds.

He said it was highly likely that the currently prescribed regime of meds was prolonging his recovery in that he appeared to have made no significant symptomatic or functional recovery despite the provision of these meds.

Dr. saw the claimant on 03/24/10 for a 5-6 week history of worsening neck pain, disturbing sleep and energy levels. He reported pain in the midline cervical, on midline upper thoracic back, on midline lumbar back and midline sacral back as well as cervicgia and myalgia. His medications included: Celebrex, Lunesta, Lyrica, Xanax and Prevacid. The examination showed right patella tendon stretch reflex 1/4, left patellar tendon stretch 1/4, right Achilles and left Achilles 1/4. Straight leg raise was negative. He had limited motion with all active motions of neck mildly with end range pain. Bilateral biceps tendon stretch, triceps tendon stretch and brachioradialis tendon stretch were 1/4. Degeneration of lumbar intervertebral disc, facet arthropathy lumbar, cervicgia, pain thoracic spine, chronic pain syndrome,

insertion of spinal neurostimulator pulse generator and chronic pain syndrome were diagnosed. Cymbalta, Norco and OxyContin were advised. Dr. re-evaluated the claimant on 04/21/10 and stated the claimant had self weaned down to 3, occasionally 4 Norco/day. He had pain in the midline upper thoracic back, midline lower thoracic and midline lumbar and sacral back and on the buttocks. He had little impairment of activities of daily living, moderate impairment of physical activities and little impairment of psychosocial function. He was a full time student. The medications included: Celebrex, Xanax and Prevacid. Lyrica had been discontinued. The examination showed a normal gait and negative sitting straight leg raise. Cervicalgia, back pain, lumbosacral radiculitis, chronic pain syndrome and long term use of high-risk meds were diagnosed. Lunesta, Norco, OxyContin and Cymbalta were advised. Dr. stated the claimant was currently taking 120 mg of OxyContin (50 percent less than in 01/10), had decreased his intermediate acting Norco down to 3 – 4 and stopped Lyrica. This was largely due to analgesic effect from the lumbar spinal cord stimulator. He said it provided significant relief, but was never expected to eliminate all lumbar and lower extremity pain. He indicated the compensable injuries also include cervical and thoracic spine and will most likely continue to need analgesic meds to maintain his function. He stated the claimant continued to comply with opioid treatment agreement and took medications safely. He stated the claimant was a single parent and full time student and planned to return to the workforce after completion of his education. Dr. stated the medications continue to provide significant analgesia allowing him to maintain his function both at home and at school.

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

The reviewer finds that prescription drugs, Norco, Lunesta, Cymbalta, and OxyContin are not medically necessary based upon review of the records. The claimant was diagnosed with cervical strain and lumbar strain in 2004. MRIs of the claimant's cervical and lumbar spine have demonstrated only mild degenerative changes. One would expect cervical and lumbar strains to resolve within three months with appropriate conservative care including physical therapy, anti-inflammatories, and work limitations. At this point, the claimant may continue to experience discomfort from the cervical or lumbar degenerative changes. However, treatment with narcotic pain medications and benzodiazepine sleep aides does not conform to ODG. Cymbalta is typically prescribed for neuropathic pain. There is no evidence of any type of spinal nerve root compression from the claimant's degenerative lumbar and cervical spine disease. Based on the ODG and the records reviewed, the reviewer finds that prescription drugs, Norco, Lunesta, Cymbalta, and OxyContin are not medically necessary.

Official Disability Guidelines Treatment in Worker's Comp 2010 Updates, (i.e. Pain – Criteria for use of Opioids, Opioids for Chronic Pain, Insomnia Treatment, Antidepressants for Chronic Pain)

CRITERIA FOR USE OF OPIOIDS

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: 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 circumstance
- (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

Opioids for Chronic Pain –

Recommendations for general conditions:

- Neuropathic pain: Opioids have been suggested for neuropathic pain that has not responded to first-line recommendations (antidepressants, anticonvulsants). 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.

- Chronic back pain: Appears to be efficacious but limited for short-term pain relief. Long-term efficacy is unclear (>16 weeks), and there is also limited evidence for the use of opioids for chronic low back pain. (Martell-Annals, 2007) 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. (Martell-Annals, 2007) (Chou, 2007) There are three studies comparing Tramadol to placebo that have reported pain relief, but this increase did not necessarily improve function. (Deshpande, 2007)

- Headaches: not recommended, in particular, due to the risk of medication overuse headache. (Lake, 2008) (Olesen, 2006)

- Osteoarthritis: 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.

- Nociceptive pain: 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).

- Mechanical and compressive etiologies: rarely beneficial

Chronic pain can have a mixed physiologic etiology of both neuropathic and nociceptive components. In most cases, analgesic 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 (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 (≤ 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.

Insomnia Treatment - Recommend that treatment be based on the etiology, with the medications recommended below. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. (Lexi-Comp, 2008) Primary insomnia is generally addressed pharmacologically. Secondary insomnia may be treated with pharmacological and/or psychological measures. The specific component of insomnia should be addressed: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; & (d) Next-day functioning. Non-Benzodiazepine sedative-hypnotics (Benzodiazepine-receptor

agonists): First-line medications for insomnia. This class of medications includes zolpidem (Ambien® and Ambien® CR), zaleplon (Sonata®), and eszopiclone (Lunesta®). Benzodiazepine-receptor agonists work by selectively binding to type-1 benzodiazepine receptors in the CNS. All of the benzodiazepine-receptor agonists are schedule IV controlled substances, which means they have potential for abuse and dependency. Although direct comparisons between benzodiazepines and the non-benzodiazepine hypnotics have not been studied, it appears that the non-benzodiazepines have similar efficacy to the benzodiazepines with fewer side effects and short duration of action.

Anti-depressants for chronic pain - Recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. (Feuerstein, 1997) (Perrot, 2006) Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week, whereas antidepressant effect takes longer to occur. (Saarto-Cochrane, 2005) Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment. Side effects, including excessive sedation (especially that which would affect work performance) should be assessed. (Additional side effects are listed below for each specific drug.) It is recommended that these outcome measurements should be initiated at one week of treatment with a recommended trial of at least 4 weeks. The optimal duration of treatment is not known because most double-blind trials have been of short duration (6-12 weeks). It has been suggested that if pain is in remission for 3-6 months, a gradual tapering of anti-depressants may be undertaken. (Perrot, 2006) (Schnitzer, 2004) (Lin-JAMA, 2003) (Salerno, 2002) (Moulin, 2001) (Fishbain, 2000) (Taylor, 2004) (Gijssman, 2004) (Jick-JAMA, 2004) (Barbui, 2004) (Asnis, 2004) (Stein, 2003) (Pollack, 2003) (Ticknor, 2004) (Staiger, 2003) Long-term effectiveness of anti-depressants has not been established. (Wong, 2007) The effect of this class of medication in combination with other classes of drugs has not been well researched. (Finnerup, 2005) The "number needed to treat" (NNT) methodology (calculated as the reciprocal value of the response rate on active and placebo) has been used to calculate efficacy of the different classes of antidepressants. (Sindrup, 2005)

Specifically studied underlying pain etiologies: (also see below for specific drugs)

Neuropathic pain: Recommended (tricyclic antidepressants) as a first-line option, especially if pain is accompanied by insomnia, anxiety, or depression. (Saarto-Cochrane, 2007) (ICSI, 2007) Other recent reviews recommended both tricyclic antidepressants and SNRIs (i.e. duloxetine and venlafaxine) as first line options. (Dworkin, 2007) (Finnerup, 2007)

Non-neuropathic pain: Recommended as an option in depressed patients, but effectiveness is limited. Non-neuropathic pain is generally treated with analgesics and anti-inflammatories. In guidelines for painful rheumatic conditions recommended by Perrot, it was suggested that antidepressants may be prescribed as analgesics in non-depressed patients, with the first-line choice being tricyclics initiated at a low dose, increasing to a maximally tolerated dose. (Perrot, 2006)

Specific studied disease state

Fibromyalgia: There have been 25 controlled trials that have studied the use of antidepressants for fibromyalgia, including 3 meta-analyses. Except for good results found with duloxetine and fibromyalgia (Arnold, 2007), the results generally show limited effectiveness on only a minority of patients for this condition, and most of these studies evaluated tricyclics. (Perrot, 2006) (Moulin, 2001) A review of two double blind, placebo controlled trials concluded that duloxetine was safe and effective in women with fibromyalgia for up to 12 weeks (with long-term studies needed). (Arnold, 2007) There appears to be a large placebo effect of this class of medications in treatment of this condition. (Saarto-Cochrane, 2007) Another review indicated that there is strong evidence that amitriptyline is effective for fibromyalgia; more information is needed regarding the role of SNRIs and SSRIs, so tricyclics may also be used for the treatment of fibromyalgia. (Goldenberg, 2007)

Low Back Pain: Chronic: A systematic review indicated that tricyclic antidepressants have demonstrated a small to moderate effect on chronic low back pain (short-term pain relief), but the effect on function is unclear. This effect appeared to be based on inhibition of norepinephrine reuptake. SSRIs have not been shown to be effective for low back pain (there was not a significant difference between SSRIs and placebo) and SNRIs have not been evaluated for this condition. (Chou, 2007) Reviews that have studied the treatment of low back pain with tricyclic antidepressants found them to be slightly more effective than placebo for the relief of pain. A non-statistically significant improvement was also noted in improvement of functioning. SSRIs do not appear to be beneficial. (Perrot, 2006) Acute: Not routinely recommended. (Chou, 2007)

Radiculopathy: Antidepressants are an option, but there are no specific medications that have been proven in high quality studies to be efficacious for treatment of lumbosacral radiculopathy. (Dworkin, 2007)

Osteoarthritis: No studies have specifically studied the use of antidepressants to treat pain from osteoarthritis. (Perrot, 2006) In depressed patients with osteoarthritis, improving depression symptoms was found to decrease pain and improve functional status. (Lin-JAMA, 2003)

Selective serotonin and norepinephrine reuptake inhibitors (SNRIs)

Duloxetine (Cymbalta®): FDA-approved for anxiety, depression, diabetic neuropathy, and fibromyalgia. Used off-label for neuropathic pain and radiculopathy. Duloxetine is recommended as a first-line option for diabetic neuropathy. (Dworkin, 2007) No high quality evidence is reported to support the use of duloxetine for lumbar radiculopathy. (Dworkin, 2007) More studies are needed to determine the efficacy of duloxetine for other types of neuropathic pain.

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

ACOEM-AMERICA 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)