

# P&S Network, Inc.

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## Notice of Independent Review Decision

**DATE OF REVIEW:** June 2, 2008

**IRO CASE #:**

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

This case was reviewed by a Pain Management Doctor, Licensed in Texas and Board Certified. The reviewer has signed a certification statement stating that no known conflicts of interest exist between the reviewer and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent (URA), any of the treating doctors or other health care providers who provided care to the injured employee, or the URA or insurance carrier health care providers who reviewed the case for a decision regarding medical necessity before referral to the IRO. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

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

Medication Lortab 10/500 mg, one qid and qhs #150  
Medication Soma 350 mg, one tid #90  
Three follow up office visits from 5/2/08 to 8/2/08

### **REVIEW OUTCOME**

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

Overtuned (Disagree)

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

- o Submitted medical records were reviewed in their entirety.
- o Treatment guidelines were provided to the IRO.
- o Undated list of providers, and addresses, and phone numbers
- o May 2, 2008 utilization review letter from
- o May 20, 2008 utilization review letter from
- o August 28, 2007 through April 8, 2008 progress reports from the Institute , , M.D. and , RN, FNP-C
- o February 29, 2008 report by , M.D.
- o July 16, 1997 through May 6, 2008 medication history
- o April 24, 2000 medical legal report by , M.D., Ph.D.

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

According to the medical records, the patient sustained an industrial injury on xx/xx/xx. The records include a May 2, 2008 utilization review report regarding a request for Lortab and Soma with three follow-up visits from May 2, 2008 to August 2, 2008. According to the report, a spinal cord stimulator trial in June 2000 was not successful. An MRI from November 2002 reveals hemilaminectomy at L5-S1 with lateral recess and foraminal disc bulge at L3-4 on the left. There was hardware removal in August 2002 and a sleeve nerve root block on June 7, 2006 with good results for 1 1/2 weeks. He underwent radiofrequency thermocoagulation at L5-S1 on January 23, 2006 which provided one to two weeks of benefit and the same procedure in December 2005 at L4-5 and L5-S1 produce one to two weeks of relief. An EMG dated January 22, 2003 notes L5 radiculopathy. He has undergone multiple injections of various types. Current medications were listed as Soma and Lortab. Surgeries consisted of four prior back surgeries resulting in L4-5 fusion. The reviewing physician referenced the Official Disability Guidelines which reportedly state that Soma is not recommended for use for longer than a two to three week period. Lortab is not generally recommended except for short use for severe cases, not to exceed two weeks. Continuation of opioids is considered if the patient has returned to work and if the patient has improved functioning and pain. The reviewer stated that the hydrocodone

would be supported if the claimant had returned to work or if this medication offered functional improvement or improvement of pain.

The case was again reviewed on May 20, 2008 and another non-certification rendered. The reviewing physician stated that there was a lack of evidence to support efficacy of muscle relaxant medications for chronic low back pain. There was a lack of documented objective or functional improvement from the use of Lortab.

In reviewing the patient's medical records, there is an April 24, 2000 designated doctor evaluation report. Medications were listed as Celebrex, Lortab 10, Norflex, baclofen, Soma, Elavil, Daypro, Effexor, Norvasc, and atenolol. His past medical history is significant for hypertension and hepatitis C. The physician recommended diagnostic blocks of the facet joints and sacroiliac joints.

A medication history was included in the medical records. The patient has taken multiple medications consistently since 1997, including opioids and muscle relaxants. The records include several progress reports between August 2007 and April 2008 from a pain management clinic. An August 28, 2007 report states that the patient remains chronic stable on medication regimen. He does well on his medications with no adverse or side effect reactions. He continues to be seen on an every other month basis, and it is working well for him at present. He manages medications with no problems. The medications allow him a level of activity and quality of life that would otherwise not be available to him. In October 2007, the physician noted that there has certainly been functional improvement in social and activities of daily living levels. He is presently not working due to his pain and disability, however. The report notes that breakthrough spasm is one of the bigger problems that the patient faces, and Soma does well to continue to manage these effectively. A December 18, 2007 report states that multiple other medications have been attempted on this patient. The combination at this time is the only thing that provides him the benefits without any of the adverse or side effect reactions. The report states that Soma is the only muscle relaxant that the patient is able to tolerate or that has had any effect for him. It works well for spasms, which are occasionally severe. A February 12, 2008 report notes that there is the possibility of surgical intervention.

A February 29, 2008 surgical consultation report states that the patient complains of severe pain rated at an 8/10 in the low back with radiation into the left lower extremity. The report reviews an MRI which reportedly revealed degenerative disc disease at L2-3, L3-4, with mild lateral recess stenosis. There was no frank spinal stenosis. He has post laminectomy changes at L4-5. The report states that the patient does not require any kind of surgical intervention. The surgeon stated that pain management is likely what he needs. The report states that the patient had a good trial of the spinal cord stimulator and it did not work. It appears that the pain management clinic is considering an updated trial of spinal cord stimulation.

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

The patient has had a recent surgical consultation and has been deemed to not be a surgical candidate. The surgeon opined that the patient is best served with pain management at this time. He has been seen by the pain management office on a regular basis and various treatments continue to be explored as an alternative to ongoing medication. There are indications in the records that the patient is stable on his medications and that this combination of medications has been found to be the most effective. The physician has stated that the patient's activities of daily living improve with these medications. As noted in the Official Disability Guidelines, an indication for continuation of opioids is if the patient has improved functioning and pain. This appears to be the case for this claimant. Although his intake of opioid medication is somewhat elevated, several alternatives have been explored and continue to be investigated. Until an effective treatment is found, it is reasonable for the patient to maintain his opioid utilization.

The records reflect that the patient's most significant ongoing problem is with episodes of muscle spasm. He has been prescribed Soma on an as needed basis to address these spasms. There is documentation that this medication has been effective for this failed back patient. The Official Disability Guidelines state that muscle relaxants should be used for a two to three week period and also advise short-term treatment of acute exacerbations in chronic pain. Given that the patient has acute exacerbations of spasm, two to three-week periods of treatment with Soma are appropriate.

The Official Disability Guidelines also state that follow-ups at approximately 1 1/2 to two month intervals are appropriate for patients that are on ongoing opioid medication. While the requested number of follow-up visits exceeds this recommendation slightly, the patient will require regular follow-up while he is on this medication regimen and while further treatment options are trialed. Therefore, my determination is to overturn the decisions to non-certify Medication Lortab 10/500 mg, one qid and qhs #150, Medication Soma 350 mg, one tid #90, and three follow up office visits.

The IRO's decision is consistent with the following guidelines:

#### **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
- \_\_\_X\_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

Official Disability Guidelines/Low Back Chapter: Opioids

Not generally recommended except for short use for severe cases, not to exceed 2 weeks. See the Pain Chapter for more information and studies. When used only for a time-limited course, opioid analgesics are an option in the management of patients with acute low back problems. The decision to use opioids should be guided by consideration of their potential complications relative to other options. Patients should be warned about potential physical dependence and the danger associated with the use of opioids while operating heavy equipment or driving. The studies found that patients taking opioid analgesics did not return to full activity sooner than patients taking NSAIDs or acetaminophen. In addition, studies found no difference in pain relief between NSAIDs and opioids. Finally, side effects of opioid analgesics were found to be substantial, including the risk for physical dependence. These side effects are an important concern in conditions that can become chronic, such as low back problems. (Bigos, 1999) For more information, and Criteria for Use of Opioids, see the Pain Chapter.

Official Disability Guidelines/Pain Chapter: 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. See Opioids for neuropathic pain.
- Chronic back pain: Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited. 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) See Medication overuse headache.
- 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 a 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 Opioids for osteoarthritis for citations.
- 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.

(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 Low Back Chapter. See Criteria for Use of Opioids.

## 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) Is there likelihood of abuse or an adverse outcome? See Substance abuse (tolerance, dependence, addiction).

(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 had a psychological evaluation and has been given a diagnosis of somatoform disorder. (3) 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).

(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.
- (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.
- (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.

### 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
- (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)

#### Official Disability Guidelines/Low Back Chapter: Muscle Relaxants

Recommended as an option in acute cases of moderate to severe LBP. OK for acute spasms. A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain concludes that available evidence supports the effectiveness of muscle relaxants in acute LBP. (Schnitzer, 2004) (Airaksinen, 2006) Muscle relaxants are commonly used for the treatment of low back problems. Pharmacologically, these are usually benzodiazepines, other sedative medications, or antihistamine derivatives. The therapeutic objective of muscle relaxants is to reduce low back pain by relieving muscle spasm. However, the concept of skeletal muscle spasm is not universally accepted as a cause of symptoms, and the most commonly used muscle relaxants have no peripheral effect on muscle spasm. Muscle relaxants are an option in the treatment of patients with acute low back problems. While probably more effective than placebo, muscle relaxants have not been shown to be more effective than NSAIDs. No additional benefit is gained by using muscle relaxants in combination with NSAIDs over using NSAIDs alone. Muscle relaxants have potential side effects, including drowsiness in up to 30 percent of patients. When considering the optional use of muscle relaxants, the clinician should balance the potential for drowsiness against a patient's intolerance of other agents. (VanTulder, 2000) (Bigos, 1999) Muscle relaxants are effective in acute LBP. Cyclobenzaprine is associated with a number needed to treat of 3 after two weeks for symptom improvement and is associated with drowsiness and dizziness. Carisoprodol is also effective but has abuse and dependency potential. Metaxalone and low-dose cyclobenzaprine have fewer adverse effects. (Kinkade, 2007) For more information, see the Pain Chapter: Muscle relaxants.

#### Official Disability Guidelines/Pain Chapter: Muscle Relaxants

Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute LBP and for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) See the Low Back Chapter. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. (Homik, 2004) Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in patients driving motor vehicles or operating heavy machinery. Drugs with the most limited published evidence in terms of clinical effectiveness include chlorzoxazone, methocarbamol, dantrolene and baclofen. (Chou, 2004)

Carisoprodol (Soma®, Soprodal 350™, Vanadom®, generic available) is metabolized to meprobamate an anxiolytic that is a schedule IV controlled substance. Carisoprodol is classified as a schedule IV drug in 10 states as of 2008. There is a school of thought that its main effect is due to generalized sedation. This drug was approved for marketing before the FDA required clinical studies to prove safety and efficacy. Withdrawal symptoms may occur with abrupt discontinuation. (See, 2008) (Reeves, 2003) See Weaning of medications. Soma has been noted to be a street drug of abuse and is often combined with acetaminophen and codeine, a combination labeled as "Soma-Coma". (Schears, 2004)

Side Effects: drowsiness, psychological and physical dependence, & withdrawal with acute discontinuation.

Dosing: 350 mg four times a day. (See, 2008) This drug is not recommended for use for longer than a 2 to 3 week period.