SENT VIA EMAIL OR FAX ON
Jun/03/2009

True Decisions Inc.

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DATE OF REVIEW:
Jun/02/2009
IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
1. 30 tablets of Proxtonix 40 mg; 2.60 tablets of SOMA 350mg; 3. 60 tablets of Lyrica 75mg; 4. 90 tablets of Klonopin 2mg; 5. 150 tablets of Norco 10/325mg. All medications are a prospective request for the dates 4/17/09 and 6/16/09.

DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
Board Certified in Physical Medicine and Rehabilitation
Subspecialty Board Certified in Pain Management
Subspecialty Board Certified in Electrodiagnostic Medicine
Residency Training PMR and ORTHOPAEDIC SURGERY

REVIEW OUTCOME:

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

[ ] Upheld (Agree)

[ ] Overturned (Disagree)

[X] Partially Overturned (Agree in part/Disagree in part)

Hydrocodone, Lyrica, and SOMA are medically necessary.
Klonopin and Protonix are not medically necessary.

INFORMATION PROVIDED TO THE IRO FOR REVIEW
OD Guidelines
Denial letters-3/10/09 and 4/24/09
-3/08-12/08; 2/09-4/09
Counseling-3/09
Peer Review Rept.-3/09
Ortho Spine-5/08

PATIENT CLINICAL HISTORY SUMMARY
This man was injured in xxxx. He underwent a laminectomy and then a secondary repair of a pseudomeningocele as a complications. He had ongoing post laminectomy syndrome and arachnoiditis. There was a comment about a motor vehicle accident in 2001. The medications are requested for the management of his pain, muscle spasms and reflux

esophagitis.

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

There are at time conflicting opinions in the medication use in the treatment of chronic pain.

I Hydrocodone

Hydrocodone is an opiate. Its value in chronic pain has been debated for the past 20 years. Even the ODG shows the dichotomy in thought. This man, as documented by Dr., does meet the criteria for the use of opiates in chronic pain. There are criteria when to stop the medication, but he does not meet the adverse behaviors associated with this. Dr. documents the improvement on the pain medications. While ideally, this man should be off the medication, it appears to be providing relief.

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) Recent studies document a 423% increase in expenditures for opioids for back pain, without demonstrated improvements in patient outcomes or disability rates. (Deyo, 2009) With opioid therapy for nonspecific low back pain compared with no opioids, the odds of chronic work loss were six times greater for claimants with schedule II ("strong") opioids; were 11-14 times greater for claimants with opioid prescriptions of any type during a period of >or=90 days; and 3 years after injury, costs of claimants with schedule II opioids averaged $19,453 higher than costs of claimants in the no opioids group. (Volinn, 2009) For more information, and Criteria for Use of Opioids, see the Pain Chapter.

II Soma/Carisoprodol

Muscle relaxers are generally considered in the treatment of acute back pain with spasms. They can provide muscle pain relief, but the mechanism is not clear. They are generally indicated for the acute back pain flareups in the chronic individual. Soma has the extra issue of being related to merpobromate, a tranquilizer from 50 years ago. It can lead to dependency. The difficulty is that many people report subjective feelings of improvement on this medication in the absence of any spasticity. It is not clear if this is from the central effect of the drug on relaxation or on the muscle itself. Personal experience has shown that many of my patients will not get relief from alternative muscle relaxers. While the ODG criteria suggest that it is not useful in the long run, many people worsen when it is stopped.

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…. Carisoprodol is also effective but has abuse and dependency potential….

Muscle relaxants (for pain

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) …

ANTISPASMODICS: Used to decrease muscle spasm in conditions such as LBP although it appears that these medications are often used for the treatment of musculoskeletal conditions whether spasm is present or not. The mechanism of action for most of these agents is not known. (Chou, 2004)

Carisoprodol (Soma®, Soprodal 350™, Vanadom®, generic available): Suggested for use as an adjunct to rest, physical therapy, analgesics, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions. (AHFS, 2008) A 250 mg formulation was FDA approved in 9/07 for treatment of acute, painful musculoskeletal conditions such as backache. Neither of these formulations is recommended for longer than a 2 to 3 week period. Carisoprodol is metabolized to meprobamate an anixolytic that is a schedule IV controlled substance. Carisoprodol is classified as a schedule IV drug in several states but not on a federal level. It is suggested that its main effect is due to generalized sedation as well as treatment of anxiety. 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) For more details, see Carisoprodol, where it is “Not recommended.” See also Weaning of medications.

Carisoprodol (Soma®)

Not recommended. This medication is FDA-approved for symptomatic relief of discomfort associated with acute pain in musculoskeletal conditions as an adjunct to rest and physical therapy. (AHFS, 2008) This medication is not indicated for long-term use. Carisoprodol is a commonly prescribed, centrally acting skeletal muscle relaxant whose primary active metabolite is meprobamate (a schedule-IV controlled substance). Carisoprodol is now scheduled in several states but not on a federal level. It has been suggested that the main effect is due to generalized sedation and treatment of anxiety. Abuse has been noted for sedative and relaxant effects. In regular abusers the main concern is the accumulation of meprobamate. Carisoprodol abuse has also been noted in order to augment or alter effects of other drugs. This includes the following: (1) increasing sedation of benzodiazepines or alcohol; (2) use to prevent side effects of cocaine; (3) use with tramadol to produce relaxation and euphoria; (4) as a combination with hydrocodone, an effect that some abusers claim is similar to heroin (referred to as a “Las Vegas Cocktail”); & (5) as a combination with codeine (referred to as “Soma Coma”). (Reeves, 1999) (Reeves, 2001) (Reeves, 2008) (Schears, 2004) There was a 300% increase in numbers of emergency room episodes related to carisoprodol from 1994 to 2005. (DHSS, 2005) Intoxication appears to include subdued consciousness, decreased cognitive function, and abnormalities of the eyes, vestibular function, appearance, gait and motor function. Intoxication includes the effects of both carisoprodol and meprobamate, both of which act on different neurotransmitters. (Bramness,

2007) (Bramness, 2004) A withdrawal syndrome has been documented that consists of insomnia, vomiting, tremors, muscle twitching, anxiety, and ataxia when abrupt discontinuation of large doses occurs. This is similar to withdrawal from meprobamate. (Reeves, 2007) (Reeves, 2004) There is little research in terms of weaning of high dose carisoprodol and there is no standard treatment regimen for patients with known dependence. Most treatment includes treatment for symptomatic complaints of withdrawal. Another option is to switch to phenobarbital to prevent withdrawal with subsequent tapering. A maximum dose of phenobarbital is 500 mg/day and the taper is 30 mg/day with a slower taper in an outpatient setting. Tapering should be individualized for each patient. (Boothby, 2003) For more information and references, see Muscle relaxants. See also Weaning of medications.

III LYRICA (pregablin)

There are several typographical or transcription errors in the records describing this as Lyrical and not Lyrica. This medication has been approved by the FDA for seizures, fibromyalgia, post herpetic neuralgia, and diabetic neuropathy. It is often used off label as a means of controlling neuropathic pain. There are no studies that I am aware of that prove its use or disprove its usefulness in the treatment of neuropathic pain other than for the conditions mentioned. Its use can be cited in text books. While there is no evidence based information to support its use, there is none refuting its use as well. It has been helping this person per Dr.,(6/23/08) and its use can continue.

Anti-epilepsy drugs (AEDs) for pai

Anti-epilepsy drugs (AEDs) are also referred to as anti-convulsants.

Recommended for neuropathic pain (pain due to nerve damage), but not for acute nociceptive pain (including somatic pain). (Gilron, 2006) (Wolfe, 2004) (Washington, 2005) (ICSI, 2005) (Wiffen-Cochrane, 2005) (Attal, 2006) (Wiffen-Cochrane, 2007) (Gilron, 2007) (ICSI, 2007) (Finnerup, 2007) There is a lack of expert consensus on the treatment of neuropathic pain in general due to heterogeneous etiologies, symptoms, physical signs and mechanisms. Most randomized controlled trials (RCTs) for the use of this class of medication for neuropathic pain have been directed at postherpetic neuralgia and painful polyneuropathy (with diabetic polyneuropathy being the most common example). There are few RCTs directed at central pain and none for painful radiculopathy. (Attal, 2006) The choice of specific agents reviewed below will depend on the balance between effectiveness and adverse reactions. See also specific drug listings below: Gabapentin (Neurontin®); Pregabalin (Lyrica®); Lamotrigine (Lamictal®); Carbamazepine (Tegretol®); Oxcarbazepine (Trileptal®); Phenytoin (Dilantin®); Topiramate (Topamax®); Levetiracetam (Keppra®); Zonisamide (Zonegran®); & Tiagabine (Gabitril®)

Specifically studied disease states: (also see below for specific drugs

Painful polyneuropathy: AEDs are recommended on a trial basis (gabapentin/pregabalin) as a first-line therapy for painful polyneuropathy (with diabetic polyneuropathy being the most common example). The other first-line options are a tri-cyclic antidepressant (if tolerated by the patient), or a SNRI antidepressant (such as duloxetine). (Attal, 2006) (Jensen, 2006)

Chronic non-specific axial low back pain: A recent review has indicated that there is insufficient evidence to recommend for or against antiepileptic drugs for axial low back pain. (Chou, 2007) ..

Spinal cord injury: Gabapentin is recommended for chronic neuropathic pain. (Levendoglu, 2004

CRPS: Gabapentin has been recommended (Serpell, 2002)

Postop pain: AEDs may also be an option for postoperative pain, resulting in decreased opioid consumption. (Peng, 2007) (Buvanendran, 2007

SPECIFIC ANTI-EPILEPSY DRUGS:…

Pregabalin (Lyrica®, no generic available) has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. This medication is designated as a Schedule V controlled substance because of its causal relationship with euphoria. (Blommel, 2007) This medication also has an anti-anxiety effect. Pregabalin is being considered by the FDA as treatment for generalized anxiety disorder and social anxiety disorder…

IV Klonopin

This is a benzodiazepine that is used for anxiety and spasms. As noted above, it can interact and increase side effects when used with Soma. Dr. did not elaborate on how it was helping other than it was medically necessary in his opinion (12/4/08). The medication is not approved for long term use. Without knowing the intent of its use, I am unable to agree with its ongoing use. The problems with withdrawal exist.

Anxiety medications in chronic pai

Recommend diagnosing and controlling anxiety as an important part of chronic pain treatment, including treatment with anxiety medications based on specific DSM-IV diagnosis as described below. Benzodiazepines are not recommended for long-term use unless the patient is being seen by a psychiatrist. Definition of anxiety disorders: Anxiety disorders for this entry include (1) generalized anxiety disorder (GAD); (2) panic disorder (PD); (3) post-traumatic stress disorder (PTSD); (4) social anxiety disorder (SAD); & (5) obsessive-compulsive disorder (OCD). …

Anxiety and chronic pain: Anxiety is commonly found in patients with chronic pain, with the most common disorders being specific phobia (12.5% to 15.7%), SAD (8.3% to 11.8%) and PTSD (7.3% to 10.7%). .

Benzodiazepines are often used to treat anxiety disorders; however, many guidelines discourage the long-term use of benzodiazepines due to sedation effects and potential for abuse and psychological dependence. Long-term use is often associated with withdrawal symptoms.

(d) Benzodiazepines: Effective for acute treatment. Long-term use is problematic as few patients achieve and sustain remission with monotherapy. These agents are used primarily as an adjunct for stabilization during initiation of an SSRI or SNRI. The disadvantage of use is the risk of abuse and physiological dependence with long-term use. These drugs also have no anti-depressant effect. Diazepam (Valium®, generic available): Dosing information: 5-15 mg daily. Clonzaepam (Klonopin®, generic available): Dosing information: 1-2 mg up to TID….

(c) Other agents used as secondary or alternative treatment to SSRIs: (Schneier, 2006) Benzodiazepines: Clonazepam (Klonopin®, generic available): Dosing information: See Generalized Anxiety Disorder. Anticonvulsants: Gabapentin (Neurontin®, generic available): non-FDA approved indication. Dosing information: 900-3600 mg per day in divided doses. Pregabalin (Lyrica®): Non-FDA approved indication. Dosing information: 300-600 mg.

(5) OBSESSIVE COMPULSIVE DISORDER (OCD): Characterized by recurrent obsessional ruminations, images or impulses, and/or recurrent physical or mental rituals. These ruminations interfere with social and occupational function. OCD is thought to respond

selectively to drugs that inhibit the synaptic reuptake of serotonin. An adequate trial should consist of 10-12 weeks with at least 4-6 weeks at the maximum tolerated dose. Cognitive-behavioral therapy may need to be considered. (Soomro, 2008) (Baldwin, 2005)

…

Benzodiazepine

Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. 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. 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. (Baillargeon, 2003) (Ashton, 2005) See also Anxiety medications in chronic pain; & Insomnia treatment.

V PROTONIX

Dr. states this person has GERD as a result of the opiates. There is no listing of GERD as a side effect of opiates. It can effect the colon musculature.

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

[X] 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 ERVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)

[ ] OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)