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Notice of Independent Review Decision

DATE OF REVIEW: NOVEMBER 24, 2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Lortab 90862, Flexeril 90862

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

This reviewer is licensed by Texas Board of Anesthesiology and Pain Management with 40 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

On February 12, 2010, M.D., performed an Independent Medical Examination. The claimant has undergone two surgical procedures consisting of posterior instrumentation and fusion of L4-5 and L5-S1 with the last procedure being on 1/31/02. He has also undergone a spinal cord stimulator placement. He determined that the current status of the claimant is that he has subjective complaints of back pain but normal neurological examination. His current complaints and treatment are related to the original date of injury compensable injury. Medications may no longer be indicated unless he agrees to the urine drug screen. Until he submits to a urine drug screen no additional or future treatment is necessary.

On May 13, 2010, the claimant was evaluated by M.D. The claimant is requesting a refill of Oxycodone and Flexeril. The typical duration of an episode is the majority of the day. His symptoms which include a stinging sensation in his back are relieve with narcotic pain medication. His current medications include Flexeril 10 mg, Lidoderm 5% adhesive patch, Oxycodone HCI 80mg, and Cymbalta 30 mg.

On June 15, 2010, the claimant was re-evaluated by M.D. The claimant is requesting a refill of Oxycodone and Flexeril. His course has been stable and nonprogressive. No changes to his current medication regimen were changed.

On July 15, 2010, the claimant was re-evaluated by M.D. The claimant is requesting a refill of Oxycodone and Cymbalta. His symptoms have remained unchanged. No changes to his current medication regimen were changed.

On August 16, 2010, the claimant was re-evaluated by M.D. The claimant is requesting a refill of Oxycodone and Flexeril. His symptoms have remained unchanged. No changes to his current medication regimen were changed.

On August 18, 2010, the claimant the claimant was re-evaluated by M.D. Evaluation showed little change from his chronic lumbar disk disease with radiculopathy. Dr. has tried to decrease his medications, physical therapy, and evaluation with orthopedists with no change in his condition and he was unable to tolerate the decrease in mediation.

On August 26, 2010, the claimant the claimant was re-evaluated by, M.D. The prescribed medications are used to suppress excruciating pain, directly related to the claimants lumbar disk disease and have been the only successful intervention in the suppression and alleviation of pain.

On September 7, 2010, M.D. stated that the claimant has an obligation to follow protocol to include urine drug screens in the tenets of a pain contract. The claimant has not submitted to a urine test, which raises “red flags”. Until he does submit to a urine drug screen, the carrier should no long submit payment for these medications.

On September 16, 2010, the claimant was re-evaluated by M.D. He is now receiving Lortab, Flexeril, Cymbalta and Lidoderm patches. His symptoms are unchanged.

On September 26, 2010, the claimant was re-evaluated by M.D. He is requesting a change in medications as Lortab caused nausea and vomiting. He needs referral to a pain management doctor so that he can get the battery changed in his spinal stimulator. He was prescribed Hydrocodone/ Acetaminophen 10mg/325mg.

On September 29, 2010, M.D., a physical medicine/rehabilitation physician performed a utilization review on the claimant Rational for Denial: Although the claimant's pain has been documented to be stable the chronic use of Flexeril is no clinically indicated or supported by the guidelines. Flexeril is only indicated for treatment of short-term use and is not recommended to be used longer than 2-3 weeks. Therefore, it is not certified.

On October 18, 2010, M.D., a family practice physician performed a utilization review on the claimant Rational for Denial: The proposed mediations are not recommended for chronic use but rather short term treatment. Therefore, it is not certified.

PATIENT CLINICAL HISTORY:

The claimant sustained an injury to the lumbar spine when he fell off a stool with painting a wall.

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

Flexeril is only indicated for treatment of short-term use and is not recommended to be used longer than 2-3 weeks. Per the ODG Guidelines opioids which includes Lortab is not recommended for long term use. Based on the above-mentioned the previous decisions are upheld.

Per the ODG:

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. (Schnitzer, 2004) (Van Tulder, 2004) (Airaksinen, 2006) 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) According to a recent review in *American Family Physician*, skeletal muscle relaxants are the most widely prescribed drug class for musculoskeletal conditions (18.5% of prescriptions), and the most commonly prescribed antispasmodic agents are carisoprodol, cyclobenzaprine, metaxalone, and methocarbamol, but despite their popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. (See2, 2008)

Classifications: Muscle relaxants are a broad range of medications that are generally divided into antispasmodics, antispasticity drugs, and drugs with both actions. (See, 2008) (van Tulder, 2006)

ANTISPASTICITY DRUGS: Used to decrease spasticity in conditions such as cerebral palsy, MS, and spinal cord injuries (upper motor neuron syndromes). Associated symptoms include exaggerated reflexes, autonomic hyperreflexia, dystonia, contractures, paresis, lack of dexterity and fatigability. (Chou, 2004)

Baclofen (Lioresal®, generic available): The mechanism of action is blockade of the pre- and post-synaptic $GABA_B$ receptors. It is recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. Baclofen has been noted to have benefits for treating lancinating, paroxysmal neuropathic pain (trigeminal neuralgia, non-FDA approved). (ICSI, 2007)

Side Effects: Sedation, dizziness, weakness, hypotension, nausea, respiratory depression and constipation. This drug should not be discontinued abruptly (withdrawal includes the risk of hallucinations and seizures). Use with caution in patients with renal and liver impairment.

Dosing: Oral: 5 mg three times a day. Upward titration can be made every 3 days up to a maximum dose of 80 mg a day. (See, 2008)

Dantrolene (Dantrium®, generic available): Not recommended. The mechanism of action is a direct inhibition of muscle contraction by decreasing the release of calcium from the sarcoplasmic reticulum.

Side Effects: A black-box warning has been issued about symptomatic fatal or nonfatal hepatitis.

Dosing: 25 mg a day for 7 days, 25 mg three times a day for 7 days, 50 mg three times a day for 7 days and then 100 mg three times a day. (See, 2008)

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)

Cyclobenzaprine (Flexeril®, Fexmid™, generic available, ER as Amrix®): Recommended for a short course of therapy. Immediate release (eg, Flexeril, generic) recommended over extended release (Amrix) due to recommended short course of therapy (also note substantial increase in cost for extended release without corresponding benefit for short course of therapy). Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. amitriptyline). Cyclobenzaprine is more effective than placebo in the management of back pain, although the effect is modest and comes at the price of adverse effects. It has a central mechanism of action, but it is not effective in treating spasticity from cerebral palsy or spinal cord disease. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement. The greatest effect appears to be in the first 4 days of treatment. (Browning, 2001) (Kinkade, 2007) (Toth, 2004) See Cyclobenzaprine. Cyclobenzaprine has been shown to produce a modest benefit in treatment of fibromyalgia. Cyclobenzaprine-treated patients with fibromyalgia were 3 times more likely to report overall improvement and to report moderate reductions in individual symptoms (particularly sleep). A meta-analysis concluded that the number needed to treat for patients with fibromyalgia was 4.8. (ICSI, 2007) (Tofferi, 2004)

Side Effects: Include anticholinergic effects (drowsiness, urinary retention and dry mouth). Sedative effects may limit use. Headache has been noted. This medication should be avoided in patients with arrhythmias, heart block, heart failure and recent myocardial infarction. Side effects limit use in the elderly. (See, 2008) (Toth, 2004)

Dosing: 5 mg three times a day. Can be increased to 10 mg three times a day. This medication is not recommended to be used for longer than 2-3 weeks. (See, 2008)

Methocarbamol (Robaxin®, Relaxin™, generic available): The mechanism of action is unknown, but appears to be related to central nervous system depressant effects with related sedative properties. This drug was approved by the FDA in 1957.

Side Effects: Drowsiness, dizziness and lightheadedness.

Dosing: 1500 mg four times a day for the first 2-3 days, then decreased to 750 mg four times a day. (See, 2008)

Metaxalone (Skelaxin®, generic available) is reported to be a relatively non-sedating muscle relaxant. The exact mechanism of action is unknown, but the effect is presumed to be due to general depression of the central nervous system. Metaxalone was approved by the FDA in 1964 and data to support approval were published in the mid-1960s. (Toth, 2004)

Side Effects: Dizziness and drowsiness, although less than that compared to other skeletal muscle relaxants. Other side effects include headache, nervousness, nausea, vomiting, and GI upset. A hypersensitivity reaction (rash) has been reported. Use with caution in patients with renal and/or hepatic failure.

Dosing: 800 mg three to four times a day (See, 2008)

Chlorzoxazone (Parafon Forte®, Paraflex®, Relax™DS, Remular S™, generic available): this drug works primarily in the spinal cord and the subcortical areas of the brain. The mechanism of action is unknown but the effect is thought to be due to general depression of the central nervous system. Advantages over other muscle relaxants include reduced sedation and less evidence for abuse. (See, 2008)

Side Effects: Drowsiness and dizziness. Urine discoloration may occur. Avoid use in patients with hepatic impairment.

Dosing: 250-750 mg three times a day to four times a day.

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.

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

Dosing: 250 mg-350 mg four times a day. (See, 2008)

Orphenadrine (Norflex®, Banflex®, Antiflex™, Mio-Rel™, Orphenate™, generic available): This drug is similar to diphenhydramine, but has greater anticholinergic effects. The mode of action is not clearly understood. Effects are thought to be secondary to analgesic and anticholinergic properties. This drug was approved by the FDA in 1959.

Side Effects: Anticholinergic effects (drowsiness, urinary retention, dry mouth). Side effects may limit use in the elderly. This medication has been reported in case studies to be abused for euphoria and to have mood elevating effects. (Shariatmadari, 1975)

Dosing: 100 mg twice a day; combination products are given three to four times a day. (See, 2008)

ANTISPASTICITY/ANTISPASMODIC DRUGS:

Tizanidine (Zanaflex®, generic available) is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. (Malanga, 2008) Eight studies have demonstrated efficacy for low back pain. (Chou, 2007) One study (conducted only in females) demonstrated a significant decrease in pain associated with subacute and chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain. (Malanga, 2002) May also provide benefit as an adjunct treatment for fibromyalgia. (ICSI, 2007)

Side effects: somnolence, dizziness, dry mouth, hypotension, weakness, hepatotoxicity (LFTs should be monitored baseline, 1, 3, and 6 months). (See, 2008)

Dosing: 4 mg initial dose; titrate gradually by 2 – 4 mg every 6 – 8 hours until therapeutic effect with tolerable side-effects; maximum 36 mg per day. (See, 2008) Use with caution in renal impairment; should be avoided in hepatic impairment. Tizanidine use has been associated with hepatic aminotransaminase elevations that are usually asymptomatic and reversible with discontinuation. This medication is related to clonidine and should not be discontinued abruptly. Weaning should occur gradually, particularly in patients that have had prolonged use. (Zanaflex-FDA, 2008)

Benzodiazepines: Not recommended due to rapid development of tolerance and dependence. There appears to be little benefit for the use of this class of drugs over nonbenzodiazepines for the treatment of spasm. (See, 2008) See Benzodiazepines.

This topic is covered under multiple headings. See more specific entries, as follows: **Opioids, criteria for use**; Opioids for chronic pain; Opioids for neuropathic pain; Opioids for osteoarthritis; Opioids, cancer pain vs. nonmalignant pain; Opioids, dealing with misuse & addiction; Opioids, differentiation: dependence & addiction; Opioids, dosing; Opioids, indicators for addiction; Opioids, long-term assessment; Opioids, pain treatment agreement; Opioids, psychological intervention; Opioids, specific drug list; Opioids, screening for risk of addiction (tests); Opioids, state medical boards guidelines; Opioids, steps to avoid misuse/addiction; Detoxification; Substance abuse (tolerance, dependence, addiction); Weaning of medications; Implantable drug-delivery systems (IDDSs); Methadone; Rapid detox; Testosterone replacement for hypogonadism (related to opioids); Opioid hyperalgesia & Opioids, specific drug list. Opioid drugs are also referred to as opiate analgesics, narcotic analgesics, or schedule C (II -IV) controlled substances. Opioid analgesics are a class of drugs (e.g., morphine, codeine, and methadone) that have a primary indication to relieve symptoms related to pain. Opioid drugs are available in various dosage forms and strengths. They are considered the most powerful class of analgesics that may be used to manage both acute and chronic pain. These medications are generally classified according to potency and duration of dosage duration.

Overall Classification:

Pure-agonists: include natural and synthetic opioids such as morphine sulfate (MS Contin®), hydromorphone (Dilaudid®), oxymorphone (Numorphan®), levorphanol (Levo-Dromoran®), codeine (Tylenol w/Codeine 3®), hydrocodone (Vicodin®), oxycodone (OxyContin®), methadone (Dolophine HCl®), and fentanyl (Duragesic®). This group of opioids does not have a ceiling effect for their analgesic efficacy nor do they antagonize (reverse) the effects of other pure opioids. (Baumann, 2002) Morphine is the most widely used type of opioid analgesic for the treatment of moderate to severe pain due to its availability, the range of doses offered, and its low cost.

Partial agonists-antagonists: agents that stimulate the analgesic portion of opioid receptors while blocking or having little or no effect on toxicity. This group of opiates includes buprenorphine (Suboxone®). Partial agonists-antagonists have lower abuse potential than pure-agonists, however the side effects of this class of analgesics include hallucinations and dysphoria. *Opioid antagonists* such as naloxone are included in this class. They are most often used to reverse the effects of agonists and agonist-antagonist derived opioids. (Baumann, 2002)

Mixed agonists-antagonists: another type of opiate analgesics that may be used to treat pain. They include such drugs as butorphanol (Stadol®), dezocine (Dalgan®), nalbuphine (Nubain®) and pentazocine (Talwin®). (Baumann, 2002) Mixed agonists-antagonists have limited use among chronic pain patients because of their ceiling effect for analgesia that results in the analgesic effect not increasing with dose escalation.

Central acting analgesics: an emerging fourth class of opiate analgesic that may be used to treat chronic pain. This small class of synthetic opioids (e.g., Tramadol) exhibits opioid activity and a mechanism of action that inhibits the reuptake of serotonin and norepinephrine. Central analgesics drugs such as Tramadol (Ultram®) are reported to be effective in managing neuropathic pain. (Kumar, 2003) Side effects are similar to traditional opioids.

Opioid Classifications: Short-acting/Long-acting opioids:

Short-acting opioids: also known as "normal-release" or "immediate-release" opioids are seen as an effective method in controlling both acute and chronic pain. They are often used for intermittent or breakthrough pain. These agents are often combined with other analgesics such as acetaminophen and aspirin. These adjunct agents may limit the upper range of dosing of short-acting agents due to their adverse effects. The duration of action is generally 3-4 hours. Short-acting opioids include Morphine (Roxanol®), Oxycodone (OxyIR®, Oxyfast®), Endocodone®, Oxycodone with acetaminophen, (Roxilox®, Roxicet®, Percocet®, Tylox®, Endocet®), Hydrocodone with acetaminophen, (Vicodin®, Lorcet®, Lortab®, Zydone®, Hydrocet®, Norco®), Hydromorphone (Dilaudid®, Hydrostat®). (Baumann, 2002)

Long-acting opioids: also known as "controlled-release", "extended-release", "sustained-release" or "long-acting" opioids, are a highly potent form of opiate analgesic. The proposed advantage of long-acting opioids is that they stabilize medication levels, and provide around-the-clock analgesia. Long-acting opioids include: Morphine (MSContin®, Oramorph SR®, Kadian®, Avinza®), Oxycodone (Oxycontin®), Fentanyl (Duragesic Patch®), Hydromorphone (Palladone®). Note: On 01/26/10 Purdue Pharma suspended Palladone® from the US market due to adverse effects with alcohol. (FDA, 2010)

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)