MAXIMUS Federal Services

| Case Number: | CM15-0211276 | | |
|---|---|---|---|
| Date Assigned: | 10/30/2015 | Date of Injury: | 01/31/2008 |
| Decision Date: | 12/18/2015 | UR Denial Date: | 10/16/2015 |
| Priority: | Standard | Application Received: | 10/27/2015 |

## HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
State(s) of Licensure: Massachusetts
Certification(s)/Specialty: Anesthesiology, Pain Management

## CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 72 year old male, who sustained an industrial injury on 1-31-08. He reported low back pain. The injured worker was diagnosed as having post-laminectomy syndrome of the lumbar region, lumbago, and sciatica. Treatment to date has included epidural steroid injections, use of a cane, left total knee replacement in 2010, L3-5 decompression in 2008, and medication including Cymbalta, Omeprazole, Norco, and Tizanidine. On 8-27-15 pain was rated as 5 of 10. On 9-24-15 pain was rated as 7-8 of 10 with medication and 9-10 of 10 without medication. The injured worker had been taking Norco and Cymbalta since at least March 2015 and Tizanidine, since at least July 2015. On 9-24-15, the injured worker complained of pain in the low back and bilateral legs. On 9-25-15 the treating physician requested authorization for Norco 10-325mg #120, Tizanidine 4mg #60, and Cymbalta 30mg (delayed release) #60. On 10-16-15 the requests were non-certified by utilization review.

## IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

**Norco 10/325mg #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

**Decision rationale:** According to the MTUS Chronic Pain Medical Treatment Guidelines section on Opioids, On-Going Management, page 74-97, (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 injured worker'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 injured worker'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 injured workers 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. (d) Home: To aid in pain and functioning assessment, the injured worker should be requested to keep a pain dairy 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 in-injured worker 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 non-opioid 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. Additionally, the MTUS states that continued use of opioids requires (a) the injured worker has returned to work, (b) the injured worker has improved functioning and pain. There is no current documentation of baseline pain, pain score with use of opioids, functional improvement on current regimen, side effects or review of potentially aberrant drug taking behaviors as outlined in the MTUS and as required for ongoing treatment. Therefore, at this time, the requirements for treatment have not been met and therefore not medically necessary.

**Tizanidine 4mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

**Decision rationale:** According to the MTUS, 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. 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 chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain. 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). 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 amino transaminase elevations that are usually asymptomatic and reversible with discontinuation. he MTUS recommends non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in injured workers with chronic LBP. 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. Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in injured workers 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. According to the documents available for review, the injured worker has been utilizing Zanaflex for long-term treatment of chronic pain condition. This is in contrast to the MTUS recommendations for short-term treatment of acute exacerbations. Therefore, at this time, the requirements for treatment have not been met, and are not medically necessary.

**Cymbalta 30mg (delayed release) #60:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antidepressants for chronic pain.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antidepressants for chronic pain.

**Decision rationale:** According to the MTUS, Cymbalta is recommended as an option in first-line treatment option in neuropathic pain. Duloxetine (Cymbalta) is a norepinephrine and serotonin reuptake inhibitor antidepressant (SNRIs). It has FDA approval for treatment of depression, generalized anxiety disorder, and for the treatment of pain related to diabetic neuropathy, with effect found to be significant by the end of week 1 (effect measured as a 30% reduction in baseline pain The medication has been found to be effective for treating

fibromyalgia in women with and without depression, 60 mg once or twice daily. (Arnold, 2005) On June 13, 2008, the FDA approved a new indication for duloxetine Hcl delayed-release capsules (Cymbalta; [redacted]) for the management of fibromyalgia in adults. 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. No high quality evidence is reported to support the use of duloxetine for lumbar radiculopathy. More studies are needed to determine the efficacy of duloxetine for other types of neuropathic pain. According to the documents available for review, the injured worker has neuropathic pain stemming from post-laminectomy syndrome, an MTUS approved indications for the use of this medication. Therefore, at this time, the requirements for treatment have been met and are medically necessary.