

Case Number:	CM15-0088799		
Date Assigned:	05/13/2015	Date of Injury:	07/13/2009
Decision Date:	06/12/2015	UR Denial Date:	04/22/2015
Priority:	Standard	Application Received:	05/08/2015

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: North Carolina
 Certification(s)/Specialty: Family Practice

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 40 year old male who sustained an industrial injury on 7/13/2009. His diagnoses, and/or impressions, are noted to include: significant myofascial para-cervical & right trapezius muscle pain and spasms; bilateral shoulder adhesive capsulitis, status-post arthroscopic lysis of lesions and manipulation; status-post cervical discectomy and fusion (1/27/12); cervicalgia; lumbar sprain/strain myofasciitis with low back and bilateral leg pain; bilateral wrist/hand/hip tendinitis; and situational depression with fatigue and insomnia. No current imaging studies are noted. His treatments have included a gluten & dairy-free diet; rheumatologic evaluation; and medication management with toxicology screenings. Progress notes of 4/9/2015 noted the return visit for continued medication management, with stated complaints of persistent neck and bilateral shoulder pain; and overall muscle soreness throughout his legs, arms, neck and low back. The objective findings were noted to include tenderness with taut muscle bands and spasms to the para-spinal musculature; limited/painful range-of-motion; and weakness of the left upper extremity. The physician's requests for treatments were noted to include the continuation of Cymbalta and Norco for the ability of daily function and exercise. The history notes that in 10/2014 he was strongly encouraged to decrease the use of Norco to use only on days of exercise activity.

IMR ISSUES, DECISIONS AND RATIONALES

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

Cymbalta 50mg #30: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines anti-depressants Page(s): 27.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines cymbalta Page(s): 43-44.

Decision rationale: The California chronic pain medical treatment guidelines section on Duloxetine states: Duloxetine (Cymbalta); 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 starting dose is 20-60 mg/day, and no advantage has been found by increasing the dose to twice a day, except in fibromyalgia. 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) The most frequent side effects include nausea, dizziness and fatigue. GI symptoms are more common early in treatment. The side effect profile of Duloxetine is thought to be less bothersome to patients than that of tricyclic antidepressants. Note: On October 17, 2005, [REDACTED] and the U. S. Food and Drug Administration (FDA) notified healthcare professionals of revision to the precautions/Hepatotoxicity section of the prescribing information for Cymbalta. Post marketing reports of hepatic injury (including hepatitis and cholestatic jaundice) suggest that patients with preexisting liver disease who take Duloxetine may have an increased risk for further liver damage. The new labeling extends the Precaution against using Cymbalta in patients with substantial alcohol use to include those patients with chronic liver disease. It is recommended that Cymbalta not be administered to patients with hepatic insufficiency. See also Antidepressants for chronic pain for general guidelines, as well as specific Duloxetine listing for more information and references. 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. The FDA notes that although Duloxetine was effective for reducing pain in patients with and without major depressive disorder, the degree of pain relief may have been greater in those with comorbid depression. Treatment of fibromyalgia with Duloxetine should be initiated at 30 mg/day for 1 week and then uptitrated to the recommended 60-mg dose. (Waknine, 2008) Note: This drug was recently included in a list of 20 medications identified by the FDA's Adverse Event Reporting System that are under FDA investigation. (FDA, 2008) The requested medication is a first line option in the treatment of neuropathic pain per the California MTUS. Per the progress notes, the patient has persistent and constant neuropathic pain. The patient has no indication of hepatic disease so there would be no major contraindications to the medication. For these reasons, criteria for use of the medication have been met and the request is medically necessary.

Norco 10/325mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids Page(s): 80.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids Page(s): 76-84.

Decision rationale: The California chronic pain medical treatment guidelines section on opioids states for ongoing management: 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. 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) The long-term use of this medication class is not recommended per the California MTUS unless there documented evidence of benefit with measurable outcome measures and improvement in function. There is no documentation of significant subjective improvement in pain such as VAS scores. There is also no objective measure of improvement in function. For these reasons, the criteria set forth above of ongoing and continued used of opioids have not been met. Therefore the request is not medically necessary.