

Case Number:	CM15-0070807		
Date Assigned:	04/20/2015	Date of Injury:	05/20/2001
Decision Date:	05/19/2015	UR Denial Date:	04/07/2015
Priority:	Standard	Application Received:	04/14/2015

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: Ohio, North Carolina, Virginia
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 (IW) is a 42-year-old female who sustained an industrial injury on 05/20/2001. Diagnoses include cervical strain, migraine headaches, and chronic pain. Treatment to date has included medications and Toradol injections. Diagnostics included functional capacity evaluation. According to the progress notes dated 2/26/15, the IW reported continued and worsened neck pain, numbness, and tingling in the hands; her medications were not authorized by Worker's Comp. She stated she felt as if she was going through withdrawals. A request was made for Duloxetine HCl 60mg, #30, Gralise 600mg, #90 and Cyclobenzaprine HCl 10mg, #90 for myospasms.

IMR ISSUES, DECISIONS AND RATIONALES

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

Duloxetine HCl 60mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti depressants.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-depressants Page(s): 14-16.

Decision rationale: Anti-depressants are recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. Duloxetine (Cymbalta) is 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. (Dworkin, 2007) No high quality evidence is reported to support the use of duloxetine for lumbar radiculopathy. (Dworkin, 2007) More studies are needed to determine the efficacy of duloxetine for other types of neuropathic pain. In this instance, the injured worker has the diagnoses of chronic pain, cervical strain, and migraine headaches. Although she has numbness and tingling in the hands, there are no diagnoses given to suggest neuropathic pain, anxiety, depression, or fibromyalgia. In short, no recognized indications for Duloxetine are provided in the available medical record. As such, Duloxetine HCL 60 mg, #30, is not medically necessary.

Gralise 600mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti epilepsy drugs (AEDs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epileptic drugs Page(s): 18-22.

Decision rationale: Gabapentin (Neurontin, Gabarone, Gralise, generic available) has been shown to be effective for treatment of diabetic painful neuropathy and post-herpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. (Backonja, 2002) (ICSI, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Attal, 2006) This RCT concluded that gabapentin monotherapy appears to be efficacious for the treatment of pain and sleep interference associated with diabetic peripheral neuropathy and exhibits positive effects on mood and quality of life. (Backonja, 1998) It has been given FDA approval for treatment of post-herpetic neuralgia. The number needed to treat (NNT) for overall neuropathic pain is 4. It has a more favorable side-effect profile than Carbamazepine, with a number needed to harm of 2.5. (Wiffen 2-Cochrane, 2005) (Zaremba, 2006) Gabapentin in combination with morphine has been studied for treatment of diabetic neuropathy and post-herpetic neuralgia. When used in combination the maximum tolerated dosage of both drugs was lower than when each was used as a single agent and better analgesia occurred at lower doses of each. (Gilron-NEJM, 2005) Recommendations involving combination therapy require further study. Mechanism of action: This medication appears to be effective in reducing abnormal hypersensitivity (allodynia and hyperalgesia), to have anti-anxiety effects, and may be beneficial as a sleep aid. (Arnold, 2007) Specific pain states: There is limited evidence to show that this medication is effective for postoperative pain, where there is fairly good evidence that the use of gabapentin and gabapentin-like compounds results in decreased opioid consumption. This beneficial effect, which may be related to an anti-anxiety effect, is accompanied by increased sedation and dizziness. Spinal cord injury: Recommended as a trial for chronic neuropathic pain that is associated with this condition. (Levendoglu, 2004) CRPS: Recommended as a trial. (Serpell, 2002) Fibromyalgia: Recommended as a trial. (Arnold, 2007) Lumbar spinal stenosis: Recommended as a trial, with statistically significant improvement found in walking distance, pain with movement, and sensory deficit found in a pilot study. (Yaksi, 2007) Side-Effect Profile: Gabapentin has a favorable side-effect profile, few

clinically significant drug-drug interactions and is generally well tolerated; however, common side effects include dizziness, somnolence, confusion, ataxia, peripheral edema, and dry mouth. (Eisenberg, 2007) (Attal, 2006) Weight gain is also an adverse effect. In this instance, the medical record does not contain reference to a diagnosis with a recognized indication for Gralise. The injured worker does have chronic pain and trigger point tenderness in the cervical spine, but no reference is made to a diagnosis of fibromyalgia, the injured worker has numbness and tingling in the hands, but no reference is made to an actual neuropathy of any kind in the available record. As such, Gralise 600mg #90 is not medically necessary.

Cyclobenzaprine HCl 10mg #90: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxant.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines cyclobenzaprine Page(s): 41-42.

Decision rationale: Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system (CNS) depressant that is marketed as Flexeril by [REDACTED]. Cyclobenzaprine (Flexeril) is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. (Browning, 2001) Treatment should be brief. There is also a post-op use. The addition of cyclobenzaprine to other agents is not recommended. (Clinical Pharmacology, 2008) Cyclobenzaprine-treated patients with fibromyalgia were 3 times as likely to report overall improvement and to report moderate reductions in individual symptoms, particularly sleep. (Tofferi, 2004) Note: Cyclobenzaprine is closely related to the tricyclic antidepressants, e.g., amitriptyline. See Antidepressants. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement in LBP and is associated with drowsiness and dizziness. In this instance, the injured worker has trigger point tenderness to the cervical musculature suggestive of possible fibromyalgia although that diagnosis is not given. There certainly seems to be myospasm of the cervical spine region. The injured worker has been off cyclobenzaprine for several months at this point, and a short-term course would be appropriate at this point. Therefore, cyclobenzaprine 10 mg #90 is medically necessary.