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| <b>Case Number:</b>   | CM14-0214829 |                              |            |
| <b>Date Assigned:</b> | 01/07/2015   | <b>Date of Injury:</b>       | 08/01/2009 |
| <b>Decision Date:</b> | 03/09/2015   | <b>UR Denial Date:</b>       | 11/19/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 12/22/2014 |

### 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: New York, Tennessee  
Certification(s)/Specialty: Emergency Medicine

### 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 patient is a 61-year-old female who was injured on August 1, 2009. The patient continued to experience pain in her back radiating to her lower extremities. Physical examination was notable for decreased range of motion of the lumbar spine, tenderness to palpation along the lumbar spine, spasm of the paraspinal muscles of the lumbar spine, and straight leg raise bilaterally. Diagnoses included lumbar radiculopathy and lumbar spinal stenosis. Treatment included medications and home exercise program. Requests for authorization for oxycodone 20 mg #60, valium 10 mg #10, cyclobenzaprine 7.5 mg #60, omeprazole 20 mg #60, and terocin patches # 120 were submitted for consideration.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**1 prescription for oxycodone 20mg #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Criteria for use.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Intervention and Guidelnes Page(s): 74-96.

**Decision rationale:** Oxycodone is an opioid medication. Chronic Pain Medical Treatment Guidelines state that opioids are not recommended as a first line therapy. Opioid should be part of a treatment plan specific for the patient and should follow criteria for use. Criteria for use include establishment of a treatment plan, determination if pain is nociceptive or neuropathic, failure of pain relief with non-opioid analgesics, setting of specific functional goals, and opioid contract with agreement for random drug testing. If analgesia is not obtained, opioids should be discontinued. The patient should be screened for likelihood that he or she could be weaned from the opioids if there is no improvement in pain of function. It is recommended for short-term use if first-line options, such as acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) have failed. In this case the patient has been taking oxycodone since at least April 2014 and not obtained analgesia. In addition there is no documentation that the patient has signed an opioid agreement. Criteria for long-term opioid use have not met; therefore, this request is not medically necessary.

**1 prescription for Valium 10mg #10: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines; Diazepam (Valium). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 24.

**Decision rationale:** Valium is diazepam, a benzodiazepine. Benzodiazepines are not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Benzodiazepines are a major cause of overdose, particularly as they act synergistically with other drugs such as opioids (mixed overdoses are often a cause of fatalities). 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. Tolerance to lethal effects does not occur and a maintenance dose may approach a lethal dose as the therapeutic index increases. Benzodiazepines are not recommended; therefore, this request is not medically necessary.

**1 prescription for cyclobenzaprine hydrochloride 7.5mg #60: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 63.

**Decision rationale:** Cyclobenzaprine is a muscle relaxant. Cyclobenzaprine is recommended as an option, for a short course of therapy. It has been found to be more effective than placebo with greater adverse side effects. Its greatest effect is in the first 4 days. Treatment should be brief.

Non-sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment (less than two weeks) of acute exacerbations in patients 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 patients driving motor vehicles or operating heavy machinery. In this case the patient has been using cyclobenzprine since at least April 2014. The duration of treatment surpasses the two weeks recommended for treatment. The medication is not recommended. The request should not be authorized.

**1 prescription for gabapentin 600mg #60: 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 Pain Interventions and Guidelines Page(s): 18-19.

**Decision rationale:** Gabapentin is an anti-epileptic medication. Gabapentin has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain and has FDA approval for treatment of post-herpetic neuralgia. Gabapentin appears to be effective in reducing abnormal hypersensitivity, to have anti-anxiety effects, and may be beneficial as a sleep aid. 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, dry mouth, and weight gain. It has been recommended for the treatment of pain from spinal cord injury, fibromyalgia, lumbar spinal stenosis, and chronic regional pain syndrome. Recommended trial period is three to eight weeks for titration, then one to two weeks at maximum tolerated dosage. If inadequate control of pain is found, a switch to another first-line drug is recommended. In this case the patient has been using gabapentin since at least June 2014 and has not obtained analgesia. Switching to another first-line medication is recommended. The request should not be authorized.

**1 prescription for omeprazole 20mg #30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation University of Michigan Health System. Gastroesophageal reflux disease (GERD). Ann Arbor (MI):University of Michigan Health System; 2012 May. 12 p.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 68.

**Decision rationale:** Omeprazole is a proton pump inhibitor (PPI). PPI's are used in the treatment of peptic ulcer disease and may be prescribed in patients who are using non-steroidal anti-inflammatory drugs and are at high risk for gastrointestinal events. Risk factors for high-risk events are age greater than 65, history of peptic ulcer, GI bleeding or perforation, concurrent use of ASA, corticosteroids, and/or an anticoagulant, or high dose/multiple NSAID (e.g., NSAID + low-dose ASA). The patient in this case was not using NSAID medication and did not have any of the risk factors for a gastrointestinal event. The request should not be authorized.

**1 prescription for Terocin patch #20: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate topicals.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 28, 105, 111-112. Decision based on Non-MTUS Citation Treatment Guidelines from the Medical Letter, April 1, 2013, Issue 128: Drugs for Pain

**Decision rationale:** Terocin is a topical multidrug compound, which contains methylsalicylate, Lidocaine, capsaicin, and menthol. Topical analgesics are recommended for neuropathic pain when anticonvulsants and antidepressants have failed. Compounded topical analgesics are commonly prescribed and there is little to no research to support the use of these compounds. Furthermore, the guidelines state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Methylsalicylate is a topical salicylate and is recommended, being significantly better than placebo in chronic pain. Lidocaine is recommended for localized peripheral pain after the evidence of a trial for first-line therapy. It is only FDA approved for the treatment of post-herpetic neuralgia. The guidelines state that further research is needed to recommend this treatment for chronic neuropathic pain. Capsaicin is recommended only as an option in patients who have not responded or cannot tolerate other treatments. It is recommended for osteoarthritis, fibromyalgia, and chronic non-specific back pain and is considered experimental in high doses. Topical analgesics containing menthol, methylsalicylate or capsaicin are generally well-tolerated, but there have been rare reports of severe skin burns requiring treatment or hospitalization. This medication contains drugs that are not recommended. Therefore the medication cannot be recommended. The request should not be authorized.