

Case Number:	CM14-0185553		
Date Assigned:	11/13/2014	Date of Injury:	07/18/2012
Decision Date:	12/19/2014	UR Denial Date:	11/03/2014
Priority:	Standard	Application Received:	11/07/2014

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. The expert reviewer is Board Certified in Family Medicine and is licensed to practice in Colorado. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

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

37 year old female with date of injury 7/18/2012 continues care with the treating physician. Patient's primary complaints include Chronic mid back pain and low back pain and right lower extremity (ankle) pain, not radicular. Patient has completed TENS unit trial with some relief and has tried acupuncture and physical therapy with some improvement in muscle tension of the back. Per the records, patient reports less pain and improved function with ability to do home exercises and perform activities of daily living when taking her current regimen of medications, twice daily low dose Gabapentin and Flexeril as needed. Per the treating physician notes, non-steroidal anti-inflammatory drugs were trialed, even with proton pump inhibitors for gastrointestinal upset, and patient was unable to tolerate. The treating physician requests refill on Gabapentin and Flexeril and approval for Diclofenac 1.5% topical analgesic.

IMR ISSUES, DECISIONS AND RATIONALES

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

1 prescription of Flexeril 5mg #90 with 3 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Flexeril (Cyclobenzaprine).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 41-42, and 64.

Decision rationale: Cyclobenzaprine (Flexeril) and other antispasmodics are recommended for musculoskeletal pain associated with spasm, but only for a short course. It has been shown to help more than placebo with back pain and fibromyalgia, but has several side effects that limit its use. Furthermore, Cyclobenzaprine works best in the first 4 days of use, so short courses recommended, no more than 2-3 weeks. No quality consistent evidence exists to support chronic use of Cyclobenzaprine. The records supplied indicate patient has been taking Cyclobenzaprine greater than 3 months. Even if patient only takes the Cyclobenzaprine intermittently, its effectiveness diminishes so quickly, that its use after 3 months would yield little benefit relative to the risks of side effects, based on the evidence. As there is no support, per the guidelines, for long term use, the request for Cyclobenzaprine is not medically necessary.

1 prescription of Gabapentin 600mg #45: 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 Treatments Page(s): 16-19.

Decision rationale: Per the guidelines, Gabapentin, an anti-epileptic drug, is recommended for treatment of neuropathic pain, as is the class of anti-epilepsy drugs (AED's). These drugs have been most studied for treatment of post herpetic neuralgia and diabetic neuropathy. Because neuropathic pain is often multifactorial with variable symptoms and physical findings, there is a lack of agreement among experts on the best treatment. There is also a lack of quality evidence for any specific treatment for neuropathic pain with most randomized control trials addressing the above mentioned post-herpetic neuralgia and other polyneuropathies, and few randomized control trials for central pain, none for treatment of radicular pain. As there is a lack of good evidence / expert agreement, per the guidelines, the choice of a specific agent for treatment of neuropathic pain and the decision to continue treatment with a specific anti-epileptic drug are generally determined by efficacy of the medication and any adverse reactions experienced. When using anti-epileptic drugs for treatment of neuropathic pain, the guidelines define a "good" response to the use of AEDs...as a 50% reduction in pain and a "moderate" response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the "trigger" for the following: (1) a switch to a different first-line agent, (2) combination therapy if treatment with a single drug agent fails.(Eisenberg, 2007) (Jensen, 2006). Per the guidelines, patient pain levels and functional improvement while taking medications should be documented at follow up appointments. Gabapentin specifically has good evidence to support its use, first-line, in neuropathic pain. (Backonja, 2002) (ICSI, 2007) (Knotkova, 2007)(Eisenberg, 2007) (Attal, 2006) It is FDA-approved for use in post-herpetic neuralgia. In addition to use in neuropathic pain, Gabapentin has evidence to support its use in spinal stenosis, fibromyalgia, spinal cord injury, and some evidence to support its use in post-operative pain to decrease anxiety and need for opioids. Per the records for the patient of concern, patient has not had a "good" or "moderate" response to the Gabapentin (40% improvement documented in one note, referred to muscle tension, and that improvement was attributed to acupuncture, not Gabapentin.) The patient has not had objective quantifiable documentation of functional improvement with the Gabapentin. Furthermore, it is

not clear from the records that patient has neuropathic pain. Her diagnoses at 10/24/2014 visit were Lumbar Disc Displacement without Myelopathy and Thoracic Sprain / Strain, with history of normal EMG. As patient has not achieved recommended level of pain relief and function improvement with Gabapentin, and as patient does not clearly have diagnosis of neuropathic pain for which the Gabapentin is indicated, the Gabapentin is therefore not medically necessary.

1 prescription of Diclofenac Sodium 1.5% 50mg #2: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 111-112.

Decision rationale: Per the MTUS Guidelines, topical analgesics are largely experimental, but may be indicated for specific conditions when other therapies have failed. However, the guidelines make it clear that if a drug or drug class in a given topical compound is "not recommended," then the entire topical treatment is not recommended. Topical Non-steroidal anti-inflammatory drugs have been studied, but only short term in small numbers, so no substantive evidence supports long term use. Use of topical non-steroidal anti-inflammatory drugs can be recommended, after first line therapies fail, for less than 12 weeks, for treatment of osteoarthritis, specifically related to the knee or elbow. No consistent quality evidence exists to use topical non-steroidal anti-inflammatory drugs for treatment of osteoarthritis of the spine, hip or shoulder, or for treatment of neuropathic pain, including radiculopathy. The only FDA-approved Topical Non-steroidal anti-inflammatory agent is Voltaren Gel 1% (diclofenac). While the records document that the patient has failed a trial of oral non-steroidal anti-inflammatory drugs because of gastrointestinal side effects, her condition, primarily back pain, is not an indicated diagnosis for use of topical non-steroidal anti-inflammatory drugs. Furthermore, the preparation requested, Diclofenac 1.5%, is not FDA-approved. Based on the lack of evidence to support its use for back pain, and as it is not an FDA-approved formulation, the Diclofenac 1.5% topical analgesic is not medically necessary.