

Case Number:	CM13-0056193		
Date Assigned:	12/30/2013	Date of Injury:	04/12/2013
Decision Date:	03/19/2014	UR Denial Date:	10/09/2013
Priority:	Standard	Application Received:	11/22/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Internal Medicine and Emergency Medicine and is licensed to practice in Florida. 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 physician 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:

This patient is a 42-year-old with a date of injury of 04/12/13. The injury was related to moving patients as a nursing assistant with subsequent back pain. A progress report associated with the request for services, dated 08/23/13, identified subjective complaints of mid and low back pain radiating into the legs, with associated numbness, neck pain, and knee pain. The objective findings included tenderness of the lumbar spine, with decreased range-of-motion. There was decreased sensation in the S1 dermatome. The diagnoses included lumbar disc protrusion with radiculopathy in L5-S1. The treatment has included five (5) sessions of physical therapy in May that were documented as "no help" on 08/19/13. She has also received an epidural steroid injection. It appears she was started on oral medications in September of 2013. A Utilization Review determination was rendered on 10/09/13 recommending non-certification of physical therapy times twelve (12); DME: lumbar spine brace; cyclobenzaprine #60; tramadol #60; odansetron (zofran) #30; pantoprazole (protonix) #60; and terocin (lidocaine/menthol) patch #10.

IMR ISSUES, DECISIONS AND RATIONALES

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

Physical therapy times twelve (12): Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation ODG

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Physical Medicine Page(s): 98-99.

Decision rationale: The Chronic Pain Guidelines recommend physical therapy with fading of treatment frequency associated with "... active therapies at home as an extension of the treatment process in order to maintain improvement levels." Specifically, for myalgia and myositis, nine to ten (9-10) visits over eight (8) weeks, and for neuralgia, neuritis, and radiculitis, eight to ten (8-10) visits over four (4) weeks. In this case, the patient has received prior physical therapy without demonstration of functional improvement. Also, recommendations are for less than twelve (12) sessions, with the recommendation for fading of treatment frequency. Likewise, there is no documentation for the home therapy component of this approach. Therefore, the record does not document the medical necessity for twelve (12) sessions physical therapy.

Lumbar spine brace: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Treatment Protocols, 5th edition.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 301.

Decision rationale: The MTUS/ACOEM Guidelines indicate that lumbar supports have not been shown to have any lasting benefit beyond the acute phase of symptom relief. There is no documentation for the medical necessity for a lumbar brace.

Cyclobenzaprine #60: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine and Muscle relaxants (for pain) Page(s): 41-42, 63-66.

Decision rationale: The Chronic Pain Guidelines indicate that cyclobenzaprine (Flexeril) is recommended as a short course of therapy. The guidelines indicate that non-sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations of low back pain. They note that in most low-back pain cases, they show no benefit beyond non-steroidal anti-inflammatory drugs (NSAIDs) in pain and overall improvement. Also, there is no additional benefit shown in combination of NSAIDs. Likewise, the efficacy diminishes over time. Limited, mixed evidence does not allow a recommendation for cyclobenzaprine for chronic use. Though it is noted that cyclobenzaprine is more effective than a placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. The guidelines also indicate that the treatment should be brief and that the addition of cyclobenzaprine to other agents is not recommended. The guidelines do note that cyclobenzaprine has been shown to produce a moderate benefit in the treatment of fibromyalgia. Sixty (60) cyclobenzaprine would be considered a short course. However, it is being initiated in

combination with other agents (tramadol), which the guidelines do not recommend. In this case, the medical records do not document the medical necessity for cyclobenzaprine (Flexeril).

Tramadol #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Work Loss Data Institute, ODG Treatment in Workers Compensation, 7th edition

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-83, 113.

Decision rationale: Tramadol (Ultram) is a centrally acting synthetic opioid analgesic. The Chronic Pain Guidelines indicate that there should be documentation and ongoing review of pain relief, functional status, appropriate use, and side effects, with the ongoing treatment of opioids. The 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. A recent epidemiologic study found that opioid treatment for chronic non-malignant pain did not seem to fulfill any of the key outcome goals including pain relief, improved quality of life, and/or improved functional capacity. The documentation submitted lacked a number of the elements listed above, including the level of functional improvement afforded by the chronic opioid therapy. The guidelines also state that with chronic low back pain, opioid therapy "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (> 16 weeks), but also appears limited." Additionally, "There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain." The guidelines further specifically state that tramadol is not recommended as a first-line oral analgesic. In this case, there is limited documentation of the elements of an initial pain assessment, or that other first-line oral analgesics have been tried and failed. There is no documented medical necessity for tramadol.

Odansetron (Zofran) #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.pubmed.com

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Odansetron; Antiemetics.

Decision rationale: Zofran (Odansetron) is a serotonin 5-HT₃ receptor antagonist used for the treatment of nausea. The Official Disability Guidelines (ODG) state that Odansetron is not recommended for nausea and vomiting secondary to opioids use. The guidelines also indicate that it is only FDA-approved for nausea and vomiting secondary to chemotherapy, postoperative use, and gastroenteritis. The medical records do not document the medical necessity for Zofran in this case.

Pantoprazole (Protonix) #60: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 68-69.

Decision rationale: Protonix is a proton pump inhibitor, and a gastric antacid. It is sometimes used for prophylaxis against the gastrointestinal (GI) side effects of non-steroidal anti-inflammatory drugs (NSAIDs) based upon the patient's risk factors. The Chronic Pain Guidelines indicate that these risk factors include (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAIDs. The use of non-selective NSAIDs without prophylaxis is considered "okay" in patients with no risk factors and no cardiovascular disease. In this case, the patient had been prescribed naproxen, but there is no documentation of any of the above risk factors. The medical records do not document the medical necessity for Protonix.

Terocin (lidocaine/menthol) patch #10: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113, 115. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

Decision rationale: Terocin is a compounded agent consisting of menthol and the active ingredients capsaicin (an irritant found in chili peppers), lidocaine (a topical anesthetic) and methylsalicylate (an anti-inflammatory). The Chronic Pain Guidelines indicate that topical analgesics are primarily recommended when other modalities could not be tolerated or have failed. They are primarily recommended for neuropathic pain. The guidelines also indicate that capsaicin topical is "Recommended only as an option in patients who have not responded or are intolerant to other treatments." It is noted that there are positive randomized trials with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific low back pain, but it should be considered experimental at very high doses. The guidelines further note that although capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in combination with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. The Official Disability Guidelines indicate that neither salicylates nor capsaicin have shown efficacy in the treatment of osteoarthritis. The guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, in this case, there is no demonstrated medical necessity for capsaicin in the compound. Lidocaine as a dermal patch has been used off-label for neuropathic pain. However, the guidelines note that no other form (creams, lotions, gels) are indicated. Further, the guidelines note that lidocaine showed no superiority over placebo for chronic muscle pain. Also, the FDA has issued warnings about the safety of these agents. The

guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, in this case, there is no demonstrated medical necessity for lidocaine as a cream in the compound. The guidelines recommend topical salicylates as being significantly better than placebo in chronic pain. However, salicylate is a non-steroidal anti-inflammatory agent. The guidelines note that this class of topicals has not been shown to have long-term effectiveness. In osteoarthritis, salicylates are superior to placebo for the first two (2) weeks, with diminishing effect over another two-week period. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. The only FDA approved agent, diclofenac, has not been evaluated for treatment of the spine, hip or shoulder. They are not recommended for neuropathic pain as there is no evidence to support their use. The Official Disability Guidelines indicate that salicylates have not shown any significant efficacy in the treatment of osteoarthritis. The guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended