

Case Number:	CM14-0068295		
Date Assigned:	07/14/2014	Date of Injury:	01/07/2005
Decision Date:	09/15/2014	UR Denial Date:	04/08/2014
Priority:	Standard	Application Received:	05/13/2014

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 Internal Medicine, has a subspecialty in 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 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:

This patient is a 46 year-old with a date of injury of 01/07/05. A progress report associated with the request for services, dated 03/18/14, identified subjective complaints of neck pain radiating into both arms with tingling as well as low back pain into the left leg. Symptoms of a sleep disorder were not documented. Objective findings included tenderness to palpation of the cervical spine and decreased range of motion. Decreased motor function was noted. Diagnoses included previous cervical fusion; cervical radiculitis; chronic constipation; and urinary incontinence. Treatment had included NSAIDs, oral analgesics, and an anti-seizure agent. A Utilization Review determination was rendered on 04/08/14 recommending non-certification of Enova RX Ibuprofen 10 % kit; Senokot 50/8.6 MG # 90; Cyclobenzaprine 7.5 MG # 60; Restone 3-100 MG # 30; Naproxen 550 MG # 60; and Tramadol # 60.

IMR ISSUES, DECISIONS AND RATIONALES

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

Enova RX Ibuprofen 10 % kit: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

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

Decision rationale: The Expert Reviewer based his/her decision on the MTUS Chronic Pain Medical Treatment Guidelines, Topical Analgesics, pages 111-113 and on the Non-MTUS Official Disability Guidelines (ODG) Pain, Topical Analgesics. The Expert Reviewer's decision rationale: The Medical Treatment Utilization Schedule (MTUS) state that "topical analgesics are recommended as an option in specific circumstances." Furthermore, MTUS states, topical analgesics are "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." Ibuprofen is an NSAID being used as a topical analgesic. The MTUS Guidelines note that the efficacy of topical NSAIDs in clinical trials has been inconsistent and most studies are small and or short duration. Recommendations primarily relate to osteoarthritis where they have been shown to be superior to placebo during the first two weeks of treatment, but either not afterward, or with diminishing effect over another two week period. The Guidelines also state that there is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. They are indicated for relief of osteoarthritis pain in joints that lend themselves to treatment (ankle, elbow, foot, hand, knee, and wrist). In neuropathic pain, they are not recommended as there is no evidence to support their use. The Official Disability Guidelines (ODG) also does not recommend them for widespread musculoskeletal pain. The only FDA approved topical NSAID is Diclofenac. In this case, there is no documentation of the failure of conventional therapy or documented functional improvement for the medical necessity of ibuprofen as an NSAID topical agent.

Senokot 50/8.6 MG # 90: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Opioid induced constipation.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: www.Senekot.com.

Decision rationale: The Expert Reviewer based his/her decision on the Non-MTUS Other Medical Treatment Guideline or Medical Evidence: www.Senekot.com. The Expert Reviewer's decision rationale: Senokot is a laxative consisting of a natural stimulant. Medical Treatment Utilization Schedule (MTUS) does not address laxatives for constipation. The non-certification was based upon lack of adequate documentation of constipation and relation to opioid use. The patient continues to take opioids for pain relief and the record does note chronic constipation. Therefore, the request does document the medical necessity for Senokot.

Cyclobenzaprine 7.5 MG # 60: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Non-sedating muscle relaxants.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine; Muscle Relaxants Page(s): 41-42; 63-66.

Decision rationale: The Expert Reviewer based his/her decision on the MTUS Chronic Pain Medical Treatment Guidelines, Cyclobenzaprine; Muscle Relaxants, pages 41-42; 63-66. The Expert Reviewer's decision rationale:Cyclobenzaprine is an antispasmodic muscle relaxant. The Medical Treatment Utilization Schedule (MTUS) states "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 NSAIDs in pain and overall improvement. Also, there is no additional benefit shown in combination of NSAIDs. Likewise, the efficacy diminishes over time. The MTUS also states "Cyclobenzaprine is indicated as a short course of therapy. Limited, mixed evidence does not allow a recommendation for Cyclobenzaprine for chronic use." Though it is noted that Cyclobenzaprine is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. They further state that treatment should be brief and that addition of cyclobenzaprine to other agents is not recommended. The Guidelines note that Cyclobenzaprine has been shown to produce a moderate benefit in the treatment of fibromyalgia. The non-certification was based upon the lack of indication of Cyclobenzaprine for chronic low back pain. However, the record does document ongoing treatment for fibromyalgia. Therefore, based upon the Guidelines, the record does document the further medical necessity for Cyclobenzaprine.

Restone 3-100 MG # 30: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Mental Illness & Stress; Insomnia Treatment, Melatonin.

Decision rationale: The Expert Reviewer based his/her decision on the Non-MTUS Official Disability Guidelines (ODG) Pain, Mental Illness & Stress; Insomnia Treatment, Melatonin. The Expert Reviewer's decision rationale:Restone contains the active ingredients melatonin, a naturally occurring hypnotic, and L-tryptophan, an amino acid that may be useful as a sleep aid. The Medical Treatment Utilization Schedule (MTUS) Guidelines do not specifically address hypnotics or these agents. The Official Disability Guidelines (ODG) state that "treatment should be based upon etiology and only after careful evaluation of the potential causes of sleep disturbance. In this case, the details of any insomnia were not documented. Therefore, the medical record does not document the medical necessity for Restone.

Naproxen 550 MG # 60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Non-steroidal antiinflammatory drugs (NSAIDs) Page(s): 67.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Acetaminophen; NSAIDs Page(s): 12; 67-73. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back, NSAIDs.

Decision rationale: The Expert Reviewer based his/her decision on the MTUS Chronic Pain Medical Treatment Guidelines, Acetaminophen; NSAIDs, pages 12; 67-73 and on the Non-MTUS Official Disability Guidelines (ODG) Low Back, NSAIDs. The Expert Reviewer's decision rationale: Naproxen (Naprosyn) is a non-steroidal anti-inflammatory agent (NSAID). The Medical Treatment Utilization Schedule (MTUS) states that "NSAIDs are recommended for use in osteoarthritis." It is also noted that they are: "Recommended at the lowest dose for the shortest period in patients with moderate to severe pain." They further indicate that there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. NSAIDs are also recommended as an option for short-term symptomatic relief on back pain. The Official Disability Guidelines (ODG) state that "studies have found that NSAIDs have more side effects than acetaminophen or placebo, but less than muscle relaxants or narcotic analgesics." Another study concluded that NSAIDs should be recommended as a treatment option after acetaminophen. The record indicates that the therapy is long-term rather than for a short period. Since NSAIDs are recommended for the shortest period possible, there must be documented evidence of functional improvement to extend therapy beyond that. In this case, there is no documentation of the functional improvement related to naproxen and therefore no medical necessity.

Tramadol # 60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 181. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Opioids, specific drug list: Tramadol.

Decision rationale: The Expert Reviewer based his/her decision on the MTUS ACOEM Practice Guidelines, Chapter 8 Neck and Upper Back Complaints, page 181 and on the Non-MTUS Official Disability Guidelines (ODG) Pain, Opioids, specific drug list: Tramadol. The Expert Reviewer's decision rationale: Tramadol (Ultram) is a centrally acting synthetic opioid analgesic. The California Medical Treatment Utilization Schedule (MTUS) Guidelines related to on-going treatment of opioids state that there "should be documentation and ongoing review of pain relief, functional status, appropriate 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." 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 (Eriksen 2006). The Guidelines further specifically state that "tramadol is not recommended as a first-line oral analgesic." The MTUS further states that "opioids are not recommended for more than 2 weeks for neck complaints." The documentation submitted lacked a number of the elements listed above, including the level of functional

improvement afforded by the chronic opioid therapy in view of the recommendations to avoid long-term therapy; likewise, that other first-line oral analgesics have been tried and failed. Therefore, the record does not document the medical necessity for tramadol.