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| Case Number: | CM14-0052820 | | |
| Date Assigned: | 07/07/2014 | Date of Injury: | 05/12/2010 |
| Decision Date: | 09/05/2014 | UR Denial Date: | 04/16/2014 |
| Priority: | Standard | Application Received: | 04/21/2014 |

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 and Emergency Medicine, has 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 51-year-old with a date of injury of 05/12/10. A progress report associated with the request for services, dated 04/02/14, identified subjective complaints of low back pain radiating into the right leg. It was noted that his NSAIDs and analgesics aggravated his stomach. Objective findings included tenderness to palpation of the lumbar spine and a positive straight leg-raising test. Sensation was diminished in the L5 dermatome. Diagnoses included lumbar disc rupture and sciatica. Treatment had included NSAIDs and oral and topical analgesics. A lumbar laminectomy was done in 2010 and a discectomy was performed in February 2014. A Utilization Review determination was rendered on 04/16/14 recommending non-certification of "Vicodin 500mg #60; Prilosec 20mg #60; Motrin 800mg #60; and Transdermal pain GKL/CAP (gabapentin, Ketoprofen, lidocaine & capsaicin)".

IMR ISSUES, DECISIONS AND RATIONALES

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

Vicodin 500mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308, Chronic Pain Treatment Guidelines Functional Improvement Measures; Opioids Page(s): 48 74-96.

Decision rationale: Vicodin 500 is an opioid analgesic in combination with acetaminophen. 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. 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 (Martell - Annals, 2007)." The MTUS further states that opioids are not recommended for more than 2 weeks for low back complaints. The patient has been on opioids in excess of 16 weeks. In this case, there is no documentation of the other elements of the pain assessment referenced above or necessity of therapy beyond 16 weeks or specific functional improvement. Therefore, there is no documented medical necessity for Vicodin. Therefore, the request is not medically necessary.

Prilosec 20mg #60: Overturned

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: The recommendations for NSAID-induced dyspepsia include changing to another NSAID, or treatment with an H2-receptor antagonist or a proton pump inhibitor. The non-certification was based upon lack of any risk factors that would justify prophylaxis. However, in this case, there is documentation of NSAID-induced gastrointestinal symptoms and the request is for active treatment rather than prophylaxis. Therefore, the medical record does document the medical necessity for omeprazole.

Motrin 800mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti inflammatory drugs).

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: Motrin 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 noted that they are recommended at the lowest dose for the shortest period in patients with moderate to severe pain." They further state 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 Motrin and therefore no medical necessity.

Transdermal pain GKL/CAP (gabapentin, ketoprofen, lidocaine & capsaicin): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: The Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that they 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. Ketoprofen 10% 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. Ketoprofen is not approved and has an extremely high incidence of photo contact dermatitis and photosensitization reactions. Gabapentin is an anti-epilepsy drug. The MTUS Guidelines state that gabapentin is: "Not recommended. There is no peer-reviewed literature to support use." The Guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, there is no documented medical necessity for the addition of gabapentin in the topical formulation for this patient. Lidocaine is a topical anesthetic. 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. In addition, the FDA has issued warnings about the safety of these agents. Capsaicin is an irritant that is the active component of chili peppers. The Guidelines for Chronic Pain state 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 (ODG) state that neither salicylates nor capsaicin have shown efficacy in the treatment of osteoarthritis. Capsaicin is available as a 0.025% formulation (for the treatment of osteoarthritis) and a 0.075% formulation primarily from studies for neuropathic pain. However, the Guidelines specifically state that there has been no studies of 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. The request does not specify the strength of the capsaicin in the compound. 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 documentation of the failure of conventional therapy, documented functional improvement, or recommendation for all the ingredients of the compound and therefore the medical necessity of the compounded formulation. Therefore, the request is not medically necessary.