

Case Number:	CM13-0044991		
Date Assigned:	03/31/2014	Date of Injury:	08/18/2007
Decision Date:	05/08/2014	UR Denial Date:	10/14/2013
Priority:	Standard	Application Received:	10/31/2013

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 51 year-old with a date of injury of 08/18/07. A progress report associated with the request for services, dated 09/17/13, identified subjective complaints of left shoulder and hand pain. Objective findings included tenderness to palpation as well as decreased strength on the left. Phalen's and Tinel's signs were positive on the left. Diagnoses included left rotator cuff syndrome and left carpal tunnel syndrome. Treatment has included oral medications including long-term opioids as well as topical therapy. A Utilization Review determination was rendered on 10/1/13 recommending non-certification of "Relafen (nabumetone) 750mg #180; Vicodin (hydrocodone) 5/500mg #60 tablets; Prilosec (omeprazole) 20mg #120; topical cream TGHOT; and Flurflex 180gm each".

IMR ISSUES, DECISIONS AND RATIONALES

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

RELAFEN (NABUMETONE) 750MG #180: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 13 Knee Complaints.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines ACETAMINOPHEN; NSAIDS Page(s): 12,67-73.

Decision rationale: Relafen (nabumetone) 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. 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 non-certification was based upon lack of recommended use of NSAIDs for chronic pain control and lack of documentation of underlying osteoarthritis. 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 response to Relafen and therefore no documented medical necessity.

VICODIN (HYDROCODONE) 5/500MG #60 TABLETS: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS, ONGOING MANAGEMENT Page(s): 91.

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: The patient is on chronic Vicodin 5/500. This is classified as 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." The MTUS further states that opioids are not recommended for more than 2 weeks for low back complaints. The patient has been on opioids well 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.

PRILOSEC (OMEPRAZOLE) 20MG #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI SYMPTOMS AND CARDIOVASCULAR RISK Page(s): 68.

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

Decision rationale: Prilosec (omeprazole), a proton pump inhibitor, is a gastric antacid. It is sometimes used for prophylaxis against the GI side effects of NSAIDs based upon the patient's risk factors. The Medical Treatment Utilization Schedule (MTUS) notes 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, there is no documentation of any of the above risk factors. Likewise, there is no documentation of any medication induced gastrointestinal side-effects or underlying gastrointestinal disease. Therefore, the medical record does not document the medical necessity for omeprazole.

TOPICAL CREAM TGHot: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113.

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; AND WWW.UPDATE.PAIN-TOPICS.ORG.

Decision rationale: TGHot is a combination of Tramadol 8%, Gabapentin 10%, Menthol 2%, Camphor 2%, and Capsaicin 0.5%. The 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." The efficacy of topical Tramadol is not specifically addressed in the MTUS or the ODG. There is some data that topical Tramadol has efficacy directly at an acute postsurgical site. However, there is insufficient data to assure that significant systemic absorption does not occur. Lacking definitive data on the efficacy of topical Tramadol, the medical record does not document neuropathic pain that has failed antidepressant or anticonvulsant therapy. Gabapentin is an anti-epilepsy drug. The California Medical Treatment Utilization Schedule (MTUS) states that topical analgesics are primarily recommended when other modalities could not be tolerated or have failed. They are primarily recommended for neuropathic pain. The MTUS Guidelines further state that gabapentin is: "Not recommended. There is no peer-reviewed literature to support use." Capsaicin is an active component of chili peppers and acts as an irritant. 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) states that neither salicylates nor capsaicin has 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 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 TG Hot.

FLURFLEX 180GM EACH: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113.

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: Fluriflex is a topical compound consisting of Flurbiprofen 15%, an NSAID, and cyclobenzaprine 10%, a muscle relaxant. The 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." Flurbiprofen 15% 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 of 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. Cyclobenzaprine 10% is a muscle relaxant being used as a topical analgesic. The MTUS Guidelines specifically state that there is no evidence for baclofen or any other muscle relaxant as a topical product. Therefore, there is no necessity for the addition of cyclobenzaprine in the topical formulation for this patient. 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 recommendation for all the ingredients of the compound and therefore the medical necessity of the compounded formulation, Fluriflex.