

Case Number:	CM13-0045343		
Date Assigned:	12/27/2013	Date of Injury:	10/31/2008
Decision Date:	06/02/2014	UR Denial Date:	10/30/2013
Priority:	Standard	Application Received:	11/12/2013

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 43 year-old with a date of injury of October 31, 2008. The most recent progress report presented for review was dated May 15, 2013, and identified subjective complaints of left knee pain. Objective findings included tenderness to palpation. There is no other documentation. Diagnoses included knee sprain/strain. Treatment has included acupuncture and topical analgesics. A Utilization Review determination was rendered on October 30, 2013 recommending non-certification of "Terocin lotion 240gm; Laxacin 100gm; gaba/cyclo/trama 10/6/10%, 180gm; flurbiprofen (nap) cream-la 180gm; and Genicin 500mg, #90".

IMR ISSUES, DECISIONS AND RATIONALES

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

PRESCRIPTION OF TEROCIN LOTION 240GM: 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; TOPICAL SALICYLATES Page(s): 105, 111-113, 115. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Topical Analgesics-Salicylates Topical Section.

Decision rationale: Terocin is a compounded agent consisting of menthol, capsaicin (an irritant found in chili peppers), lidocaine (a topical anesthetic) and methylsalicylate (an anti-inflammatory). The Chronic Pain Medical Treatment 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 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. 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. In this case, there is recommendation and therefore demonstrated medical necessity for lidocaine as a cream in the compound. The Chronic Pain Guidelines do recommend topical salicylates as being significantly better than placebo in chronic pain. In osteoarthritis, salicylates are superior to placebo for the first two weeks, with diminishing effect over another two-week period. The Official Disability Guidelines also recommend topical salicylates as an option and note that they are significantly better than placebo in acute and chronic pain. They further note however, that neither salicylates nor capsaicin have shown 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 is not recommended." Therefore, in this case, there is no documentation of the failure of conventional therapy, documented functional improvement. The request for terocin lotion 240gm is not medically necessary or appropriate.

1 PRESCRIPTION OF LAXACIN 100GM: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 77. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Opioid-Induced Constipation Treatment.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS Page(s): 77. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Opioid-Induced Constipation Treatment.

Decision rationale: Laxacin is a combination of docusate, a stool softener, and a sennoside, which is a stimulant laxative. The Medical Treatment Utilization Schedule (MTUS) and the Official Disability Guidelines (ODG) recommend prophylactic treatment of constipation with the initiation of opioids. The non-certification was based up lack of medical records. However, with the long-term use of opioids in this patient, there is documented medical necessity for Laxacin.

However, the frequency and duration is not specified. The request for laxacin 100 grams is not medically necessary or appropriate.

1 PRESCRIPTION FOR GABA/CYCLO/TRAMA 10/6/10%, 180GM: 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. Decision based on Non-MTUS Citation MTUS Official Disability Guidelines (ODG) Pain, Topical Analgesics, and the website Updates.pain-topics.org.

Decision rationale: The requested compound consists of gabapentin, an anti-seizure agent, cyclobenzaprine, a muscle relaxant, and tramadol, a centrally acting opioid analgesic. The Chronic Pain Medical Treatment 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 Chronic Pain Medical Treatment 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. The Chronic Pain Medical Treatment Guidelines state that there is no specific evidence for baclofen or any other muscle relaxant as a topical product. 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 necessity for the addition of cyclobenzaprine in the topical formulation for this patient. The efficacy of topical Tramadol is not specifically addressed in the Chronic Pain Medical Treatment Guidelines or the Official Disability Guidelines (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. Therefore, medical necessity for topical Tramadol has not been established. The Chronic Pain Medical Treatment Guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." 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. The request for gaba/cyclo/trama 10/6/10%, 180 grams is not medically necessary or appropriate.

1 PRESCRIPTION OF FLURBIPROFEN (NAP) CREAM-LA 180GM: 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. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Topical Analgesics.

Decision rationale: The Chronic Pain Medical Treatment 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 is an NSAID (non-steroidal anti-inflammatory drug) 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. The request for Flurbiprofen (NAP) cream-LA 180 grams is not medically necessary or appropriate.

1 PRESCRIPTION OF GENICIN 500MG, #90: 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 GLUCOSAMINE Page(s): 50. Decision based on Non-MTUS Citation website www.genecin.com.

Decision rationale: Genicin is a product of [REDACTED] and contains 500 mg of glucosamine sulfate (GS) in each capsule. Glucosamine is a compound found in cartilage. The Chronic Pain Medical Treatment Guidelines state that glucosamine is recommended as an option given its low risk, in patients with moderate arthritis pain. They note that studies have demonstrated highly significant efficacy for the crystalline form of glucosamine sulfate on all outcomes including pain and joint space narrowing. The greatest value has been demonstrated in arthritis of the knee. However, they note that similar studies are lacking for glucosamine hydrochloride. Further, they state that results obtained with GS may not be extrapolated to other salts (hydrochloride) or formulations (OTC or food supplements). Last, they note that studies have indicated that the effect of the combination of GS and chondroitin sulfate may be less than the effect of each treatment singly. The request for Genicin 500 mg, ninety count, is not medically necessary or appropriate.