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| Case Number: | CM13-0056235 | | |
| Date Assigned: | 12/30/2013 | Date of Injury: | 12/18/2007 |
| Decision Date: | 03/20/2014 | UR Denial Date: | 10/22/2013 |
| 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 & 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 61 year-old with a neck injury on 12/18/07. A progress report dated 09/09/13 identified subjective complaints of neck and right shoulder pain. Objective findings included right elbow and shoulder tenderness. Compression of the right brachial plexus produced symptoms. Previous nerve conduction studies showed a right cubital and carpal tunnel syndrome. Diagnoses included posttraumatic thoracic outlet syndrome with ulnar, radial, and median neuropathies. Previous studies include an MRI of the right shoulder that showed arthritis of the AC and glenohumeral joints. Treatment has included a cervical fusion. History related to the request for oral and topical therapy is not included. A Utilization Review determination was rendered on 10/22/13 recommending non-certification of "Genicin; Terocin; Flurb/Lido/Amitr/Lido; Gaba/Cyclo/Tram/Lipo; Somnicin".

IMR ISSUES, DECISIONS AND RATIONALES

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

Terocin: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Salicylate, Topical Analgesics, Glucosamine(and Chondroitin). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Treatment Index, 11th Edition(web), 2013,Chronic Pain-Salicylate topical;Compound drugs. Clin J pain,2008 Jan;PMID;18180637 PubMed-indexed for MEDLINE.US National Institute of Health(NIH) National Library of Medicine(NLM) PubM

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: 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 California Medical Treatment Utilization Schedule (MTUS) Chronic Pain section 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 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. 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 do 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 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 (ODG) states that salicylates have not shown any significant efficacy in the treatment of osteoarthritis. The Guidelines further state: "Any compounded product that

Genicin: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Salicylate, Topical Analgesics, Glucosamine(and Chondroitin). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Treatment Index, 11th Edition(web), 2013,Chronic Pain-Salicylate topical;Compound drugs. Clin J pain,2008 Jan;PMID;18180637

PubMed-indexed for MEDLINE.US National Institute of Health(NIH) National Library of Medicine(NLM) PubM

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine Page(s): 50. Decision based on Non-MTUS Citation www.genicin.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 Medical Treatment Utilization Schedule (MTUS) 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. In this case, radiologic studies have defined underlying arthritis. The original denial of services was based upon the GS only being effective in osteoarthritis of the knee. The Guidelines do not restrict the use of GS only to the knee. Therefore, in this case, there is documented medical necessity for Genicin.

Flurb/Lido/Amitr/Lido: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Salicylate, Topical Analgesics, Glucosamine(and Chondroitin). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Treatment Index, 11th Edition(web), 2013,Chronic Pain-Salicylate topical;Compound drugs. Clin J pain,2008 Jan;PMID;18180637 PubMed-indexed for MEDLINE.US National Institute of Health(NIH) National Library of Medicine(NLM) PubM

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 Clin J Pain. 2008 Jan;24(1):51-5.

Decision rationale: The requested compound consists of Flurbiprofen, an NSAID, Lidocaine, an anesthetic, and Amitriptyline, a tricyclic antidepressant, presumably with the delivery vehicle Lipoderm, a product of the [REDACTED]. 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 Official Disability Guidelines (ODG) state that topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The efficacy of topical NSAIDs in osteoarthritis has been inconsistent. 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. In neuropathic pain, they are not

recommended as there is no evidence to support their use. The only FDA approved topical NSAID is diclofenac. 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 Flurbiprofen in the topical formulation for this patient. 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 with this type of formulation. Neither the California Medical Treatment Utilization Schedule (MTUS) nor the Official Disability Guidelines (ODG) specifically addresses the use of Amitriptyline as a topical agent. A randomized, placebo-controlled crossover study examined topical 5% Amitriptyline with 5% Lidocaine topical in patients with neuropathic pain. The study found that topical Amitriptyline was not effective. Therefore, there is no demonstrated medical necessity for topical Amitriptyline. 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 or documented functional improvement for the medical necessity of the compounded formulation.

Gaba/Cyclo/Tram/Lipo: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Salicylate, Topical Analgesics, Glucosamine(and Chondroitin). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Treatment Index, 11th Edition(web), 2013,Chronic Pain-Salicylate topical;Compound drugs. Clin J pain,2008 Jan;PMID;18180637 PubMed-indexed for MEDLINE.US National Institute of Health(NIH) National Library of Medicine(NLM) PubM

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 105, 111-113, 50. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Topical Analgesics, and www.updates.pain-topics.org; J Anesth. 2010 Oct;24(5):705-8.

Decision rationale: The requested compound consists of gabapentin, an anti-seizure agent, cyclobenzaprine, a muscle relaxant, and Tramadol, a centrally acting opioid analgesic, with the delivery vehicle Lipoderm, a product of the [REDACTED]. 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 Official Disability Guidelines (ODG) state that topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. 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. The MTUS Guidelines state

that there is no 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 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. Therefore, medical necessity for topical Tramadol has not been established. 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 or documented functional improvement for the medical necessity of the compounded formulation.

Somnicin: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Salicylate, Topical Analgesics, Glucosamine (and Chondroitin). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Treatment Index, 11th Edition (web), 2013, Chronic Pain-Salicylate topical; Compound drugs. Clin J Pain, 2008 Jan; PMID: 18180637 PubMed-indexed for MEDLINE. US National Institute of Health (NIH) National Library of Medicine (NLM) PubMed

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation The Physician Reviewer based his/her decision on Official Disability Guidelines (ODG) Pain, Insomnia Treatment.

Decision rationale: Somnicin is a product of [REDACTED], and contains the active ingredients melatonin, a naturally occurring hypnotic, 5-HTP, which increases the levels of serotonin, L-tryptophan, an amino acid that may be useful as a sleep aid, vitamin B6, which promotes the production of serotonin, and magnesium, which the company states supports sleep. 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. They do not specifically address the agents in Somnicin nor affirm their efficacy. Additionally, Somnicin contains agents that are available at recommended levels in a normal diet. Therefore, in this case, the medical record does not document the medical necessity for Somnicin.