MAXIMUS Federal Services

Case Number:	CM15-0096015		
Date Assigned:	05/22/2015	Date of Injury:	05/21/2014
Decision Date:	06/30/2015	UR Denial Date:	04/24/2015
Priority:	Standard	Application Received:	05/19/2015

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
State(s) of Licensure: Pennsylvania
Certification(s)/Specialty: Internal Medicine

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 41 year old female who sustained an industrial injury on May 21, 2014 due to a trip and fall. She was diagnosed with right wrist sprain/strain, left ankle tenosynovitis, anxiety, and depression. Treatment included medications, physical therapy, and home exercise program. Ibuprofen was prescribed since October 2014, and documentation indicates that ibuoprofen was used prior to October 2014 as well. Magnetic Resonance Imaging of the right wrist on 11/11/14 was unremarkable. Magnetic Resonance Imaging of the left ankle on 11/11/14 revealed tenosynovitis of the posterior tibial tendon. At a visit on 2/17/15, the injured worker complained of ankle pain and frequent right wrist pain with numbness and tingling in the hand, depression, anxiety and insomnia. Medications were noted to decrease pain level from 6/10 to 3/10. Topical creams and patches were noted to help decrease pain and use of oral medications and to allow the injured worker to perform chores. Upon examination, there was decreased range of motion of the right wrist and left ankle and tenderness over the lateral ankle. Work status was noted as full duty. The treatment plan included prescriptions for norco, Ibuprofen, Terocin Patch, compound creams, Somnicin and Genicin Capsules and a follow up visit. On 4/24/15, Utilization Review (UR) non-certified requests for the items currently under Independent Medical Review, citing the MTUS, ODG, and additional medical literature.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ibuprofen 800mg, #60: Upheld

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

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

Decision rationale: This injured worker has chronic wrist and ankle pain. Ibuprofen has been prescribed for at least 5 months, and documentation indicates use of ibuprofen since prior to October 2014. Per the MTUS, nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended as a second line treatment after acetaminophen for treatment of acute exacerbations of chronic back pain. The MTUS does not specifically reference the use of NSAIDs for long-term treatment of chronic pain in other specific body parts. NSAIDs are noted to have adverse effects including gastrointestinal side effects and increased cardiovascular risk; besides these well-documented side effects of NSAIDs, NSAIDs have been shown to possibly delay and hamper healing in all the soft tissues including muscles, ligaments, tendons, and cartilage. NSAIDs can increase blood pressure and may cause fluid retention, edema, and congestive heart failure; all NSAIDS are relatively contraindicated in patients with renal insufficiency, congestive heart failure, or volume excess. They are recommended at the lowest dose for the shortest possible period in patients with moderate to severe pain. NSAIDs should be used for the short term only. There was documentation of use of ibuprofen for chronic pain, not for an acute exacerbation of pain. Trial of acetaminophen was not discussed. Systemic toxicity is possible with NSAIDs. The FDA and MTUS recommend monitoring of blood tests and blood pressure. There is no evidence that the prescribing physician is adequately monitoring for toxicity as recommended by the FDA and MTUS. No blood pressure readings or laboratory tests were submitted. The treating physician is prescribing oral and transdermal NSAIDs. This is duplicative, potentially toxic, and excessive, as topical NSAIDs are absorbed systemically. Due to length of use in excess of guideline recommendations, and potential for toxicity, the request for ibuprofen is not medically necessary.

Terocin Pain Patch #20: 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 anagesics Page(s): 111-113. Decision based on Non-MTUS Citation Uptodate: camphor and menthol: drug information. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

Decision rationale: Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. Terocin patch contains lidocaine and menthol. The site of application and directions for use were not specified. Lidocaine is only FDA approved for treating post-herpetic

neuralgia, and the dermal patch form (Lidoderm) is the only form indicated for neuropathic pain. There is no documentation that this injured worker has neuropathic pain or post-herpetic neuralgia. The MTUS and ODG are silent with regard to menthol. It may be used for relief of dry, itchy skin. This agent carries warnings that it may cause serious burns. There was no documentation of neuropathic pain for this injured worker, and no documentation of trial and failure of antidepressants or anticonvulsants. Due to lack of indication, the request for Terocin patches is not medically necessary.

Terocin 120ml, Capsaicin 0.025%, 120ml, Flubi (NAP), Cream LA 180grams, Gabacyclotram 180grams: 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 anagesics medications for chronic pain,salicylate topicals Page(s): 60, 104, 111-113.

Decision rationale: This injured worker has chronic wrist and ankle pain. This request is for several compounded topical products. Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. In this case, there was no documentation of neurpathic pain or of trial and failure of antidepressant or anticonvulsant medication. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. Per the MTUS, any compounded product that contains at least one drug that is not recommended, is not recommended. Terocin lotion contains Methyl Salicylate 25%, Menthol 10%, Capsaicin 0.025%, and Lidocaine 2.5%. Topical salicylates are recommended for use for chronic pain and have been found to be significantly better than placebo in chronic pain. Topical lidocaine in the form of the Lidoderm patch is indicated for neuropathic pain. The MTUS does not recommend topical lidocaine other than Lidoderm patch for neuropathic pain. Capsaicin is recommended as an option in patients who have not responded or are intolerant to other treatments. Capsaicin alone in the standard formulation readily available OTC may be indicated for some patients. The indication in this case is unknown, as the patient has not failed adequate trials of other treatments. The MTUS and ODG are silent with regard to menthol. It may be used for relief of dry, itchy skin. This agent carries warnings that it may cause serious burns. Flurbi (NAP) Cream-LA flurbiprofen, amitriptyline, and lidocaine. Flurbiprofen is a nonsteroidal anti-inflammatory drug (NSAID). Topical NSAIDS are indicated for osteoarthritis and tendinitis, in particular that of the knee and elbow or other joints that are amenable to topical treatment. There is little evidence to utilize topical NSAIDS for treatment of osteoarthritis of the spine, hip, or shoulder. Topical nonsteroidals are not recommended for neuropathic pain. Note that topical flurbiprofen is not FDA approved, and is therefore experimental and cannot be presumed as safe and efficacious. Non-FDA approved medications are not medically necessary. The MTUS and ODG do not address amitriptyline in topical form. Lidocaine is addressed above. Gabacyclotram contains gabapentin, cyclobenzaprine, and tramadol. Gabapentin is an antiepileptic drug and is not recommended in topical form; there is no peer-reviewed literature to support use.

Cyclobenzaprine is a muscle relaxant. The MTUS notes that there is no evidence for use of muscle relaxants as topical products. Tramadol is a centrally acting synthetic opioid analgesic. The MTUS and ODG do not address tramadol in topical form. As multiple drugs in these compounded topical medications are not recommended, the compounds are not recommended. Due to lack of documentation of neuropathic pain, lack of documentation of failure of first line agents, provision of multiple medications simultaneously, and lack of recommendation for some ingredients in each of these compounded topical medications, the request for Terocin 120ml, Capsaicin 0.025%, 120ml, Flubi (NAP), Cream LA 180grams, Gabacyclotram 180grams is not medically necessary.

Somnicin #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://skyerholdings.comsomnicin%E2%84%A2/.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter: somnicinpain chapter: insomnia treatment.

Decision rationale: Per the ODG, somnicin is not recommended. Somnicin, a nutritional supplement, contains melatonin, magnesium oxide, oxitriptan (the L form of 5-hydroxytryptophan), 5-hydroxytryptophan, tryptophan and Vitamin B6 (pyridoxine). It is postulated as a treatment for insomnia, anxiety and depression. The treating physician documented that this medication was prescribed for the treatment of insomnia, anxiety, and muscle relaxation. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing medication, should not be initiated without a careful diagnosis. There is no evidence of that in this case. For the treatment of insomnia, pharmacologic agents should only be used after careful evaluation of potential causes of sleep disturbance. Specific components of insomnia should be addressed. There was no documentation of evaluation of sleep disturbance in the injured worker, and components insomnia were not addressed. Due to lack of recommendation by the guidelines for this medication, and lack of sufficient evaluation of sleep disturbance, the request for somnicin is not medically necessary.

Follow Up Visit: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Procedure, Online Version.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids Page(s): 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter: office visits.

Decision rationale: The ODG notes that office visits are recommended as determined to be medically necessary. The need for a clinical office visit with a health care provider is

individualized based upon a review of the patient concerns, signs and symptoms, clinical stability, and reasonable physician judgment. The determination is also based on what medications the patient is taking, since some medicines require close monitoring. This injured worker has chronic wrist and ankle pain, with documentation of ongoing pain and limited range of motion. Medications including Norco have been prescribed. Treatment with opioid medication requires ongoing monitoring per the MTUS. As such, the request for a follow up visit is medically necessary. The Utilization Review determination also states that given the ongoing pain complaints and use of medication, one follow up office visit is medically necessary.

Genicin Capsules #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines glucosamine and chondroitin sulfate Page(s): 50.

Decision rationale: This injured worker has right wrist sprain/strain and left ankle tenosynovitis. The documentation submitted indicates that genicin contains glucosamine sodium 500 mg. The treating physician has not provided clear indications for this supplement in light of the MTUS recommendations. The MTUS recommends glucosamine for arthritis (primarily of the knee), and the glucosamine should be of a specific type defined in the MTUS. The form of glucosamine used in this case is not the proper form recommended in the MTUS, as the MTUS describes a specific chemical form on which medical evidence is based (glucosamine sulphate). Other forms, including food supplements, lack scientific credibility. There was no documentation of arthritis for this injured worker. Due to lack of specific indication, the request for genicin is not medically necessary.