

Case Number:	CM15-0105505		
Date Assigned:	06/12/2015	Date of Injury:	12/17/2008
Decision Date:	09/24/2015	UR Denial Date:	05/27/2015
Priority:	Standard	Application Received:	06/01/2015

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: California
 Certification(s)/Specialty: Emergency 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 46 year old female, who sustained an industrial injury on 12/17/2008. According to a progress report dated 02/13/2015, the injured worker complained of frequent neck pain that radiated to the right upper extremity with numbness and tingling. Neck pain was rated 5 on a scale of 1-10. Constant mid back pain was rated 5. Occasional low back pain that radiated to the bilateral lower extremities was rated 3. Occasional left shoulder pain and frequent left knee pain was rated 3. She denied side effects or gastrointestinal symptoms with the use of oral and topical medications. Pain level without medications was 9-10 and decreased to 3-4 with the use of medications. Topical creams and patches helped decrease pain and use of oral medications and allowed her to walk and sleep longer and perform more chores. Diagnoses included cervical sprain/strain, cervical radiculopathy, thoracic sprain/strain, lumbar radiculopathy, lumbar spine strain/sprain, status post left shoulder surgery March 2011 and status post left knee surgery. The treatment plan included Tramadol tablets, Terocin pain patch, Calypso 2% cream, Terocin cream, Flurbi (NAP) cream-LA, Gabacyclotram, and Somnicin capsules. Currently under review is the request for Genicin capsules, Somnicin capsules, Laxacin tablets, Flurbi NAP cream LA, Gabacyclotram, Terocin, Terocin pain patch and Mentherm gel.

IMR ISSUES, DECISIONS AND RATIONALES

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

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 Page(s): 50.

Decision rationale: Recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride (GH). (Richy, 2003) (Ruane, 2002) (Towheed-Cochrane, 2001) (Braham, 2003) (Reginster, 2007) A randomized, double-blind placebo controlled trial, with 212 patients, found that patients on placebo had progressive joint-space narrowing, but there was no significant joint-space loss in patients on glucosamine sulphate. In this case, the use of glucosamine is not indicated. The patient does not meet the diagnostic criteria set for use. As such, the request is not medically necessary.

Somnicin capsules #30: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, B vitamins & vitamin B complex.

Decision rationale: The request is for a product which contains multivitamins. The ODG states the following regarding this topic: Not recommended for the treatment of chronic pain unless this is associated with documented vitamin deficiency. There are multiple B vitamins with specific symptoms due to deficiency: (1) vitamin B1 (thiamine) - beriberi; (2) vitamin B2 (riboflavin); (3) vitamin B3 (niacin or nicotinic acid) - pellegra; (4) vitamin B5 (pantothenic acid); (5) vitamin B6 (pyridoxine); (6) vitamin B7 (biotin); (7) vitamin B9 (folic acid) - megaloblastic anemia; (8) vitamin B12 (various cobalamins) - pernicious anemia, myelopathy, neuropathy, dementia, subacute combined degeneration of the spine, and decreased cognition. Treatment of vitamin B12 deficiency is generally parenteral. Vitamin B Complex contains the above 8 vitamins plus para-aminobenzoic acid, inositol, and choline. It is frequently used for treating peripheral neuropathy but its efficacy is not clear. A recent meta-analysis concluded that there are only limited data in randomized trials testing the efficacy of vitamin B for treating peripheral neuropathy (diabetic and alcoholic). Evidence was insufficient to determine whether specific B vitamins or B complex for these conditions was beneficial or harmful. (Ang-Cochrane, 2008) See B vitamins for depression in the Mental Health and Stress Chapter. In this case, the use of this product is not indicated. This is secondary to inadequate documentation of deficiency. As such, the request is not medically necessary.

Laxacin tablets #100: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2780140/>.

Decision rationale: The request is for the use of a product usually used for constipation. Its active ingredient is Docusate sodium which is a surface-active agent laxative. The MTUS and ODG guidelines are silent regarding this topic and as such, an alternative source was used. Docusate is an effective agent and can be used safely for chronic constipation. In this case, there is inadequate documentation of a full evaluation delineating the etiology of the patient's symptoms as well as non-pharmacologic dietary treatment rendered. As such, the request is not medically necessary.

Flurbi NAP cream LA 180 gms: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-112.

Decision rationale: The request is for the use of a topical NSAID for pain relief. There are specific criteria require for use based on the guidelines. The MTUS states the following: The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. In this case, as indicated above, the patient would not qualify for the use of this medication based on the diagnosis and treatment duration. As such, the request is not medically necessary.

Gabacyclotram 180 gms: 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 Page(s): 111 to 113.

Decision rationale: The request is for the use of a compounded medication for topical use to aid in pain relief. These products contain multiple ingredients which each have specific properties and mechanisms of action. The MTUS guidelines state the following: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, the use of gabapentin is stated to be not indicated for use for the patient's condition. The guidelines state the following: "Gabapentin: Not recommended. There is no peer-reviewed literature to support use." As such, the request is not medically necessary.

Terocin 120 ml: 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 Page(s): 111-112.

Decision rationale: The request is for the use of a topical NSAID for pain relief. There are specific criteria require for use based on the guidelines. The MTUS states the following: The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. In this case, as indicated above, the patient would not qualify for the use of this medication based on the diagnosis and treatment duration. As such, the request is not medically necessary.

Terocin pain patch #20: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-112.

Decision rationale: The request is for the use of a topical NSAID for pain relief. There are specific criteria require for use based on the guidelines. The MTUS states the following: The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. In this case, as indicated above, the patient would not qualify for the use of this medication based on the diagnosis and treatment duration. As such, the request is not medically necessary.

Menthoderm gel 120 ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-112.

Decision rationale: The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. In this case, as indicated above, the patient would not qualify for the use of this medication based on the duration of treatment. As such, the request is not medically necessary.