

Case Number:	CM14-0080116		
Date Assigned:	07/18/2014	Date of Injury:	02/01/2012
Decision Date:	08/29/2014	UR Denial Date:	05/09/2014
Priority:	Standard	Application Received:	05/30/2014

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 Physical Medicine and Rehabilitation, has a subspecialty in Interventional Spine and is licensed to practice in California. 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:

The patient is a 35 year old female with an injury date on 02/01/2012. Based on the 04/25/2014 progress report provided by [REDACTED], the diagnoses are: 1. Lumbar Radiculopathy (724.4). 2. Right Knee Sprain/Strain (844.9). 3. Status Post Right Ankle/Foot ORIF Surgery August 23, 2013. According to this report, the patient complains of constant low back pain radiating to the lower extremities with numbness and tingling with pain level at a 6-7/10. The patient also complains of frequent right knee pain with numbness and tingling with pain level at 4/10 and constant right ankle/foot pain with numbness and tingling with pain at 7/10. Lumbar range of motion is limited. The SLR test is positive on the right. Tenderness of the lumbar spine was noted with spasms. Right knee and ankle range of motion are limited. There are no oral or topical medications side effects noted. There were no other significant findings noted on this report. [REDACTED] is requesting: 1. Terocin gel. 2. Flurbi (NAP) cream. 3. Gabacyclotram. 4. Genicin #905. Somnicin #30 There were no other significant findings noted on this report. The utilization review denied the request on 05/09/2014. [REDACTED] is the requesting provider, and provided treatment reports from 12/10/2013 to 04/25/2014.

IMR ISSUES, DECISIONS AND RATIONALES

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

Terocin Gel: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines The MTUS has the following regarding topical creams (p111, chronic pain section) Page(s): 111.

Decision rationale: According to the 04/25/2014 report by [REDACTED] this patient presents with constant low back pain with right knee and ankle pain. The treater is requesting Terocin gel. Regarding topical lidocaine, MTUS guidelines states: Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as Gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. MTUS further states, any compounded product that contains at least one drug (or drug class) that is not recommended, is not recommended. For salicylate, a topical NSAID, MTUS does allow it for peripheral joint arthritis/tendinitis problems. However, the patient does not present with peripheral joint problems to warrant a compound product with salicylate. Furthermore, the MTUS guidelines do not allow any formulation of Lidocaine other than in patch form. Therefore the Terocin Gel is not medically necessary and appropriate.

Flurbi Cream LA (NAP): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines The MTUS has the following regarding topical creams (p111, chronic pain section):Topical Analgesics Page(s): 111.

Decision rationale: According to the 04/25/2014 report by [REDACTED] this patient presents with constant low back pain with right knee and ankle pain. The treater is requesting Flurbi (NAP) cream. Regarding topical NSAIDS, MTUS guidelines recommends for osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment. In this case, the patient does not meet the indication for the topical medication as she does not present with any osteoarthritis or tendonitis symptoms. In addition, Lidocaine is only allowed in a patch form and not allowed in cream, lotion or gel forms. The MTUS Guidelines page 111 has the following regarding topical creams: topical analgesics are largely experimental and used with few randomized control trials to determine efficacy or safety. MTUS further states, Any compounded product that contains at least one drug (or drug class) that is not recommended, is not recommended. Flurbi Cream LA (NAP) is not medically necessary and appropriate.

Gabacyclotram: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines The MTUS has the following regarding topical creams (p111, chronic pain section): Topical Analgesics.

Decision rationale: According to the 04/25/2014 report by [REDACTED] this patient presents with constant low back pain with right knee and ankle pain. The treater is requesting Gabacyclotram. The MTUS Guidelines regarding topical analgesics states that it is, "Largely experimental in use with few randomized controlled trials to determine efficacy or safety." MTUS further states, "Any compounded product that contains at least one (or drug class) that is not recommended, is not recommended." Cyclobenzaprine is a muscle relaxant and is not recommended for any topical formulation. Furthermore, Gabapentin is not recommended as a topical formulation. Therefore Gabacyclotram is not medically necessary and appropriate.

Genicin #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine: page 50 Glucosamine (and Chondroitin Sulfate) Page(s): 50.

Decision rationale: According to the 04/25/2014 report by [REDACTED] this patient presents with constant low back pain with right knee and ankle pain. The treater is requesting Genicin #90. Regarding Glucosamine, MTUS guidelines state: Recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. In this case, the patient does not meet the indication for Glucosamine, as she does not present with knee osteoarthritis. Per MTUS guidelines, Genicin #90 is not medically necessary and appropriate.

Somnicin #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines MD Consult Drug Monograph.

MAXIMUS guideline: Decision based on the Non-MTUS Official Disability Guidelines (ODG). ODG guidelines on Vitamin B, 5-hydroxytryptophan, Melatonin.

Decision rationale: According to the 04/25/2014 report by [REDACTED] this patient presents with constant low back pain with right knee and ankle pain. The treater is requesting Somnicin #30. The MTUS, ACOEM and ODG guidelines do not discuss Somnicin. The search on the web indicates Somnicin is an oral medication of natural ingredients that help and promote sleep. Active Ingredients are Melatonin 2 mg, 5-HTP (5-hydroxytryptophan) 50 mg, L-tryptophan 100 mg, Vitamin B6 (pyridoxine) 10 mg, Magnesium 50 mg: (<http://sales.advancedrxmgt.com/salescontent/uploads/2012/04/Somnicin-Patient-InfoSheet.pdf>). Somnicin is a supplement and it is not FDA approved to treat any medical condition and cannot be considered a medical treatment for any condition. ODG guidelines do address some of these items separately, however they do not recommend melatonin-receptor agonist for more than 7-10 days, and do not recommend Vitamin B supplements. ODG guidelines do recommend 5-hydroxytryptophan as recommended to be use with caution. Given that some of the ingredients

lack guideline support, the request for Somnicin #30 is not medically necessary and appropriate.