

Case Number:	CM13-0013293		
Date Assigned:	11/06/2013	Date of Injury:	12/18/2008
Decision Date:	01/13/2014	UR Denial Date:	08/05/2013
Priority:	Standard	Application Received:	08/19/2013

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 Pain Management, has a subspecialty in Disability Evaluation, 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 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:

The patient is a 62 year old female who worked for [REDACTED] status post lower back injury on 12/18/2008. The employee had L5-S1 anterior and posterior fusion surgery performed on 11/5/2011 and 11/8/2011. At issue is whether the use of Genecin 500mg #90 for 30 days supply; Terocin lotion, somnicin capsules and ketoprofen cream is medically necessary.

IMR ISSUES, DECISIONS AND RATIONALES

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

New Terocin Lotion #240 20-day supply: Upheld

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

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

Decision rationale: Terocin lotion is a topical analgesic containing the following active ingredients: Capsaicin, Lidocaine, Menthol and Salicylate. According to MTUS Chronic Guidelines, the use of topical analgesics is largely experimental with few randomized controlled trials to determine efficacy or safety. MTUS Chronic Pain Guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is therefore not

recommended as a whole. Therefore topical Terocin lotion is not medically necessary and appropriate.

Genicin 500mg cap #90 30-day supply: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation British Medical Journal, The Use of Glucosamine for Chronic Low Back Pain: A Systematic Review of Randomised Control Trials..

Decision rationale: MTUS Guidelines are mute about Genicin therapy. The abstract of a recent study published in British Medical Journal on June 14, 2013 titled "The use of glucosamine for chronic low back pain: a systematic review of randomized control trials" ascertains whether the use of oral glucosamine influences symptoms or functional outcomes in patients with chronic low back pain (LBP) thought to be related to spinal osteoarthritis (OA). The review found that there was low quality but generally no evidence of an effect from glucosamine on function, with no change in the Roland-Morris Disability Questionnaire score in all studies. Conflicting evidence was demonstrated with pain scores with two studies showing no difference and one study with a high risk-of-bias showing both a statistically and clinically significant improvement from taking glucosamine. The study found that clinical benefit of oral glucosamine for patients with chronic lower back pain and radiographic changes of spinal osteoarthritis can neither be demonstrated nor excluded based on insufficient data and the low quality of existing studies. Based on this study, the request for Genicin 500mg #90 30 day supply is not medically necessary and appropriate.

Ketoprofen (NAP) Cream #180 20-day supply (retrospective): Upheld

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

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

Decision rationale: According to the MTUS Chronic Pain Guidelines, Ketoprofen is not currently FDA approved for a topical application. The request for Ketoprofen (NAP) Cream #180 20-day supply (retrospective) is not medically necessary and appropriate.

Somnicin cap #30 30-day supply: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Insomnia treatment..

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate.com, FDA.gov, and the University of Michigan Health Systems- Health Library..

Decision rationale: Somnicin is considered a medical food with the following active Ingredients: Melatonin 2 mg, 5-HTP (5-hydroxytryptopan) 50 mg, L-tryptophan 100 mg, Vitamin B6 (pyridoxine) 10 mg, Magnesium 50 mg. According to the USFDA website, the term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "a food which is formulated to be consumed or administered internally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation..Medical foods are not drugs and, therefore, are not subject to any regulatory requirements that specifically apply to drugs. For example, medical foods do not have to undergo premarket review or approval." MTUS Guidelines are mute about this medication. According to Up-To-Date reference, Melatonin is a hormone that is normally produced by a gland in the brain. Melatonin does not appear to be helpful in most people who have insomnia, except in people with delayed sleep phase syndrome. There is no documentation that this patient has delayed sleep phase syndrome. According to the University of Michigan Health Systems- Health Library, the dosage of L-tryptophan and 5-Hydroxytryptopan contained in Somnicin is far below the recommended dosage for use in treating insomnia (1-4 gm). Therefore Somnicin cap #30 30-day supply is not medical necessary and appropriate.