

Case Number:	CM15-0110725		
Date Assigned:	06/17/2015	Date of Injury:	08/16/2000
Decision Date:	07/15/2015	UR Denial Date:	05/21/2015
Priority:	Standard	Application Received:	06/09/2015

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: North Carolina
 Certification(s)/Specialty: Family Practice

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 51 year old female who sustained a work related injury August 16, 2000. Past history included diabetes, chronic pain syndrome, compound fracture of the right arm (undated) and fracture left ankle with open reduction internal fixation of left lateral ankle December, 2012, s/p decompressive surgery thoracolumbar laminectomy, s/p spinal cord stimulator phase II revision. According to a medical management progress report, dated May 8, 2015, the physician discusses the wheelchair type and hospital bed and mattress needed for the injured worker. She is 245 pounds and prone to skin breakdown and difficulty positioning in bed due to abdominal girth and chronic pain involving both lower extremities. A physical medicine and rehabilitation and pain management interim report, dated May 19, 2015, finds the injured worker with ongoing urinary incontinence. She is under the care of an urologist and has had a medication change regarding this issue. IPG site on the right flank side is protruding and tender in the abdomen region. Soft tissue examination reveals allodynia and hyperesthesia in the right thigh, leg, and foot. There is a bruise on the buttock on the right side and the right thigh. Motor strength of the right lower extremity is 3/5 and left lower extremity 3/5. Diagnoses are complex regional pain syndrome both lower extremities, right flank neuralgia from IPG site, surgical procedure; thoracic myelopathy; arachnoiditis. At issue, is the request for authorization for Glucosamine/Chondroitin Sulfate and Terbinafine CRE.

IMR ISSUES, DECISIONS AND RATIONALES

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

Glucos/Chond tab 500-400 day supply 30 QTY: 90 refills 4 RX date 5/11/15: Overturned

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 glucosamine Page(s): 50.

Decision rationale: The California chronic pain medical treatment guidelines section on glucosamine states: Glucosamine (and Chondroitin Sulfate) 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. (Reginster, 2001) Another RCT with 202 patients concluded that long-term treatment with glucosamine sulfate retarded the progression of knee osteoarthritis, possibly determining disease modification. (Pavelka, 2002) The Glucosamine Chondroitin Arthritis Intervention Trial (GAIT) funded by the National Institutes of Health concluded that glucosamine hydrochloride (GH) and chondroitin sulfate were not effective in reducing knee pain in the study group overall; however, these may be effective in combination for patients with moderate-to-severe knee pain. [Note: The GAIT investigators did not use glucosamine sulfate (GS).] (Distler, 2006) Exploratory analyses suggest that the combination of glucosamine and chondroitin sulfate may be effective in the subgroup of patients with moderate-to-severe knee pain. (Clegg, 2006) In a recent meta-analysis, the authors found that the apparent benefits of chondroitin were largely confined to studies of poor methodological quality, such as those with small patient numbers or ones with unclear concealment of allocation. When the analysis was limited to the three best-designed studies with the largest sample sizes (40% of all patients), chondroitin offered virtually no relief from joint pain. While not particularly effective, chondroitin use did not appear to be harmful either, according to a meta-analysis of 12 of the studies. (Reichenbach, 2007) Despite multiple controlled clinical trials of glucosamine in osteoarthritis (mainly of the knee), controversy on efficacy related to symptomatic improvement continues. Differences in results originate from the differences in products, study design and study populations. Symptomatic efficacy described in multiple studies performed with glucosamine sulphate (GS) support continued consideration in the OA therapeutic armamentarium. Compelling evidence exists that GS may reduce the progression of knee osteoarthritis. Results obtained with GS may not be extrapolated to other salts (hydrochloride) or formulations (OTC or food supplements) in which no warranty exists about content, pharmacokinetics and pharmacodynamics of the tablets. (Reginster, 2007) [Note: DONA Glucosamine Sulfate is the original crystalline glucosamine sulfate (GS), which was first developed and marketed for human use by ██████████ ██████████, funding some of the initial trials. Glucosamine hydrochloride (GH) is not proprietary, so it tends to be less expensive but there has also been less funding for quality

studies.] Recent research: This RCT assessed radiographic outcomes in OA of the knee in patients being treated with glucosamine hydrochloride (note: GH not GS), chondroitin sulfate (CS), glucosamine plus CS, celecoxib, or placebo. Over 2 years, no treatment achieved the predefined clinically important difference from placebo in terms of joint space width (JSW) loss. The effect of the combination of glucosamine plus CS may be less active than the effect of each treatment singly. Kellgren/Lawrence (K/L) grade 2 knees may represent a more potentially responsive population. Treatment effects on K/L grade 2 knees (less severe OA), but not on K/L grade 3 knees (more severe), showed a trend toward improvement relative to the placebo group. (Sawitzke, 2008) The requested medication is recommended per the California MTUS and therefore the request is medically necessary.

Terbinafine CRE 1% day supply: 15 QTY: 90 refills 4 RX date 5/11/15: Overturned

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation PDR, terbinafine.

Decision rationale: The California MTUS, ODG and the ACOEM do not specifically address the requested service. The physician desk reference states the requested medication is indicated in the treatment of topical fungal infections. The patient does have the history of topical fungal infections and skin breakdown. Therefore the request is medically necessary.