

Case Number:	CM15-0164925		
Date Assigned:	09/02/2015	Date of Injury:	11/16/2013
Decision Date:	10/05/2015	UR Denial Date:	07/21/2015
Priority:	Standard	Application Received:	08/21/2015

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 44 year old male who sustained an industrial injury on November 16, 2013. Documentation provided showed on August 21, 2014, May 01, 2014 he underwent lumbosacral epidural steroid injection. An initial orthopedic evaluation dated November 11, 2014 reported subjective complaint of lumbar back pain and right knee pain. He states currently taking Norco 4 times daily. A primary treating follow up dated April 17, 2015 reported subjective complaint of headache, low back pain radiating to bilateral legs with associated numbness and tingling; erectile dysfunction; difficulty falling asleep and daytime sleepiness; and depression, loss of memory and anxiety. He was diagnosed with the following: strain and sprain lumbar spine with right lower extremity radiculopathy, erectile dysfunction and herniated disc; strain and sprain of right knee, and sleep disturbance. The plan of care noted continuing with conservative management to include: Capsaicin cream, Lidocaine patches and Norco. There is recommendation to continue with acupuncture and chiropractic sessions. There is recommendation to seek urology consultation.

IMR ISSUES, DECISIONS AND RATIONALES

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

Genicin cap 500mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate) Page(s): 50. Decision based on Non-MTUS Citation Official Disability Guidelines, Low Back updated 8/22/14 Official Disability Guidelines, Pain Chapter updated 7/10/15 and 7/15/15.

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, doubleblind 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 a nutritional supplement containing glucosamine. While the use of glucosamine sulfate and chondroitin are recommended per the California MTUS, there is no diagnosis of osteoarthritis. Therefore the request is not medically necessary.