

<b>Case Number:</b>	CM14-0105751		
<b>Date Assigned:</b>	09/12/2014	<b>Date of Injury:</b>	03/01/2012
<b>Decision Date:</b>	05/19/2015	<b>UR Denial Date:</b>	06/26/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/07/2014

### 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. 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 3/1/12. He reported right shoulder, head, and neck pain. The injured worker was diagnosed as having cervical myospasms, disc desiccation, annular tears, disc protrusion, and neural foraminal stenosis per MRI findings. Other diagnoses included thoracic sprain/strain with myospasms, right shoulder impingement with full thickness supraspinatus tear, and sleep loss secondary to pain. Treatment to date has included cervical epidural injections, 2 sessions of physical therapy, a home exercise program, and medications. Currently, the injured worker complains of neck pain, upper/mid back pain, and right shoulder pain. The treating physician requested authorization for Cidaflex. The treatment plan included right shoulder arthroscopic rotator cuff repair.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Cidaflex:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine and Chondroitin Sulfate.

**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 knee s (more severe), showed a trend toward improvement relative to the placebo group. (Sawitzke, 2008) The requested medication is a nutritional supplement containing glucosamine and chondroitin. The patient does not have an arthritis diagnosis and therefore the request is not medically necessary.