MAXIMUS Federal Services

| Case Number: | CM15-0080638 | | |
|---|---|---|---|
| Date Assigned: | 05/01/2015 | Date of Injury: | 03/04/2010 |
| Decision Date: | 06/01/2015 | UR Denial Date: | 04/23/2015 |
| Priority: | Standard | Application Received: | 04/27/2015 |

## 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 67-year-old female injured worker suffered an industrial injury on 03/04/2010. The diagnoses included bilateral knees derangement, left wrist, left hand sprain, and left shoulder derangement. The diagnostics included left knee magnetic resonance imaging, left wrist, left shoulder, right hip, lumbar spine and left elbow. The injured worker had been treated with medications and home exercise program. On 3/25/2015, the treating provider reported there was a flare up and worsening of the symptoms. The treatment plan included Medi patches with Lidocaine, Exoten-C lotion, and Cidaflex.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Medi patches with Lidocaine 20% #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patches), Topical Analgesics Page(s): 56-57, 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 111-113.

**Decision rationale:** The California chronic pain medical treatment guidelines section on topical analgesics states: Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The requested medication contains ingredients, which are not indicated per the California MTUS for topical analgesic use. Therefore, the request is not medically necessary.

**Exoten-C lotion 120gm #8 tubes:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 111-113.

**Decision rationale:** The California chronic pain medical treatment guidelines section on topical analgesics states: Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The requested medication contains ingredients, which are not indicated per the California MTUS for topical analgesic use. Therefore, the request is not medically necessary.

**Cidaflex 400mg 400mg #360:** Upheld

**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, 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 Rotta Research Laboratorium, funding some of theinitial 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,

chondroitin. The patient does not have the diagnosis of significant osteoarthritis. Therefore, the medication is not indicated and the request is not medically necessary.