

Case Number:	CM13-0039607		
Date Assigned:	12/20/2013	Date of Injury:	04/06/1992
Decision Date:	02/04/2014	UR Denial Date:	10/15/2013
Priority:	Standard	Application Received:	10/28/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Family Medicine, and is licensed to practice in North Carolina. He 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 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 59 year old male who sustained an injury on 04/06/1992 at which time he fell from a van. His diagnoses include myalgia and myositis (729.1), organic insomnia (327.00), lumbar region sprain (847.2) and shoulder sprain (840.9). Treatments received include ketofen mild ointment (no dosing schedule provided), cidalflex (2 p qam and 1 po qpm), TENS unit, ibuprofen, acupuncture, physical therapy and home exercise program. A progress report dated 12/31/2013 from [REDACTED] notes that the patient has no pain and " that he has not had a flare up that required medication since his last visit." A utilization review dated 10/10/2013 was rendered and recommended non-certification for ketofen mild ointment and cidalflex.

IMR ISSUES, DECISIONS AND RATIONALES

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

1 month supply of ketofen mild ointment between 10-10-13 and 11-24-13: 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 topical analgesics Page(s): 111-112.

Decision rationale: The California Medical Utilization Schedule addresses topical analgesics in its chronic pain medical treatment guidelines section. Topical analgesics are considered "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, α -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, β 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 use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. [Note: Topical analgesics work locally underneath the skin where they are applied. These do not include transdermal analgesics that are systemic agents entering the body through a transdermal means. See Duragesic[®] (fentanyl transdermal system).] Non-steroidal antiinflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. (Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use. FDA-approved agents: Voltaren[®] Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical tre

1 month supply of cidalflex between 10-10-13 and 11-24-13: 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 (and chondroitin sulfate) Page(s): 50.

Decision rationale: 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 ██████████