

<b>Case Number:</b>	CM14-0184850		
<b>Date Assigned:</b>	11/12/2014	<b>Date of Injury:</b>	02/05/2004
<b>Decision Date:</b>	01/07/2015	<b>UR Denial Date:</b>	10/16/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/06/2014

### 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. The expert reviewer is Board Certified in Family Medicine and is licensed to practice in California. 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/services. He/she 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 52-year-old male who sustained an industrial injury on February 5, 2004. The patient fell on the date of injury and underwent lumbar laminectomy in 2006. The patient is diagnosed with lumbar spondylosis, other pain disorder related psychological factors, mood disorder and conditions classified elsewhere, herniation disk thoracic, lumbar spine radiculopathy, lumbar failed back syndrome, fibromyalgia and myositis, lumbar degenerative disc disease, and lumbosacral spondylosis without myelopathy. A trial of spinal cord stimulation is being considered. Utilization review was performed on October 16, 2014 at which time recommendation was made to modify the request for Terocin lotion. Recommendation was made to non-certify the request for Genecin capsule, recommendation was made to non-certify the request for topical medications ketoprofen/lidocaine/Penderm and gabapentin/ketoprofen/cyclobenzaprine/Penderm.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Terocin Lotion 240gm:** 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): 110-112. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/cdi/terocin-lotion.html>

**Decision rationale:** Terocin cream contains capsaicin/lidocaine/menthol/methyl salicylate. References state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. The guidelines also state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. References state topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Furthermore, in February 2007 the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical lidocaine. Those at particular risk were individuals that applied large amounts of this substance over large areas, left the products on for long periods of time, or used the agent with occlusive dressings. Systemic exposure was highly variable among patients. Only FDA-approved products are currently recommended. (Argoff, 2006) (Dworkin, 2007) (Khaliq-Cochrane, 2007) (Knotkova, 2007) (Lexi-Comp, 2008) Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments and the medical records do not establish that the patient has been unable to tolerate other treatments. While methyl salicylate is recommended per the CA MTUS guidelines, the request for a topical lotion which also contains lidocaine and capsaicin is not medically necessary.

**Genicin 500mg capsule #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate) Page(s): 50.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate) Page(s): 49-50. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Low Back, Glucosamine

**Decision rationale:** According to the CA MTUS guidelines, glucosamine is recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. The patient is not diagnosed with knee osteoarthrosis. The chief complaint is regarding the lumbar spine. According to ODG, glucosamine is not recommended for low back pain. Glucosamine is not significantly different from placebo for reducing pain-related disability or improving health-related quality of life in patients with chronic low back pain (LBP) and degenerative lumbar osteoarthritis, and it should not be recommended for patients with lower back pain. The request for Genicin 500mg capsule #30.

**Ketoprofen (NAP) Cream (Ketoprofen powder 20%/Lidocaine HCl 5%/Penderm bass) 180gm:** 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): 110-112.

**Decision rationale:** According to the CA MUTS guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. The guidelines specifically state that Ketoprofen is not currently FDA approved for a topical application, and it has an extremely high incidence of photocontact dermatitis. References state topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. As such, the request for Ketoprofen (NAP) Cream (Ketoprofen powder 20%/Lidocaine HCl 5%/Penderm base) 180gm is not medically necessary.