

<b>Case Number:</b>	CM13-0030641		
<b>Date Assigned:</b>	11/27/2013	<b>Date of Injury:</b>	04/24/1996
<b>Decision Date:</b>	01/16/2014	<b>UR Denial Date:</b>	09/16/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/30/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Physical Medicine & Rehabilitation 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 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/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 49-year-old male with a reported date of injury on 04/24/1996. The patient presented with mid back pain rated 5/10 and constant low back pain with pain radiation to the right lower extremity rated 7/10. The patient had diagnoses including status post thoracic spine surgery, lumbar sprain/strain, lumbar radiculitis, and lumbar disc protrusion. The physician's treatment plan included a request for a prescription of Terocin 240 mL (capsaicin 0.025%, menthol 10%, lidocaine 2.5%), a prescription of gabacyclotram 180 gm (gabapentin 10%, cyclobenzaprine 6%, tramadol 10%), a prescription of Flurbi (NAP) cream (flurbiprofen 20%, lidocaine 5%, amitriptyline 4%), and request for 90 Genicin.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**1 prescription of Terocin 240ml (Capsaicin 0.025%, Menthol 10%, Lidocaine 2.5%): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

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

**Decision rationale:** Terocin lotion is comprised of capsaicin, Lidocaine, menthol, and methyl salicylate. The California MTUS guidelines state any compounded product that contains at least

1 drug or drug class that is not recommended is not recommended. The California MTUS Guidelines note topical salicylate is significantly better than placebo in chronic pain. The California MTUS Guidelines recommend the use of capsaicin for patients with osteoarthritis, postherpetic neuralgia, diabetic neuropathy, and post mastectomy pain. The guidelines recommend the use of capsaicin only as an option in patients who have not responded or are intolerant to other treatments. The guidelines recommend the use of Lidocaine for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). 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. Within the provided documentation, it did not appear the patient had a diagnosis that would indicate the patient's need for capsaicin. Additionally, the Guidelines do not recommend the use of any other formulation of topical lidocaine except for the Lidoderm patch. The Guidelines recommend any compound containing a drug or drug class that is not recommended is not recommended. Therefore, the request for 1 prescription of Terocin 240ml (Capsaicin 0.025%, Menthol 10%, Lidocaine 2.5%) is neither medically necessary nor appropriate.

**1 prescription of Gabacyclotram 180gm (Gabapentin 10%, Cyclobenzaprine 6%, Tramadol 10%): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

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

**Decision rationale:** The California MTUS guidelines state, any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended. The guidelines note the topical use of gabapentin is not recommended, as there is no peer-reviewed literature to support use. The guidelines also note there is no evidence for use of any other muscle relaxant as a topical product. The Guidelines do not recommend the topical use of gabapentin and cyclobenzaprine. The Guidelines note any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended. Therefore, the request for 1 prescription of Gabacyclotram 180gm (Gabapentin 10%, Cyclobenzaprine 6%, Tramadol 10%) is neither medically necessary nor appropriate

**1 prescription of Flrbi (NAP) cream (Flrbiprofen 20%, Lidocaine 5%, Amitriptyline 4%): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

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

**Decision rationale:** The California MTUS guidelines note 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. The guidelines note these medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) The guidelines recommend the use of topical NSAIDs for 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 and use with neuropathic pain is not recommended, as there is no evidence to support use. The guidelines recommend the use of Lidocaine for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). 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. The guidelines note any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Within the provided documentation, it did not appear the patient had a diagnosis that would indicate the patient's need for topical flurbiprofen at this time. Additionally, the Guidelines note any other form of topical lidocaine besides the lidocaine patch is not recommended. The Guidelines note any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended. Therefore, the request for 1 prescription of Flurbi (NAP) cream (Flurbiprofen 20%, Lidocaine 5%, Amitriptyline 4%) is neither medically necessary nor appropriate.

**90 Genicin:** 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:** The California MTUS guidelines note glucosamine is 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). 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. Within the provided documentation, it did not appear the patient had moderate arthritis related pain. Therefore, the request for 90 Genicin is neither medically necessary nor appropriate.