

<b>Case Number:</b>	CM15-0181752		
<b>Date Assigned:</b>	09/23/2015	<b>Date of Injury:</b>	06/27/2005
<b>Decision Date:</b>	11/18/2015	<b>UR Denial Date:</b>	08/20/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/15/2015

### 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: California  
 Certification(s)/Specialty: Emergency Medicine

### 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 62-year-old male, with a reported date of injury of 06-27-2005. The diagnoses include lumbar disc disease, lumbar radiculitis, post laminectomy syndrome, and cervical disc disease. Treatments and evaluation to date have included Anaprox, Norco (since at least 03-2015), Prilosec, Lyrica, lumbar surgeries, physical therapy, and cervical spine surgery. The diagnostic studies to date have included a urine drug screen on 03-17-2015 with consistent findings; a urine drug screen on 06-08-2015 with consistent findings; and a urine drug screen on 08-05-2015 with consistent findings. The progress report dated 08-05-2015 indicates that the injured worker complained of moderate low back pain and cervical pain, which increased with activity. The injured worker also complained of shoulder pain. He rated his pain 5 out of 10 (08-05-2015); and 6 out of 10 (06-08-2015). The objective findings include tenderness to palpation over the incision, a well-healed scar, a slow gait pattern, cervical flexion at 10 degrees, cervical extension at 20 degrees, cervical right lateral bend at 20 degrees, cervical left lateral bend at 15 degrees, tenderness to palpation of the cervical spine, full shoulder with pain, decreased deep tendon reflexes throughout the upper extremities, and diminished sensation over the bilateral L5-S1 distribution to light touch. The report indicates that the injured worker underwent electrodiagnostic studies on 12-02-2013 which showed post-acute denervation to C5-6 distribution, bilateral carpal tunnel and Guyon canal syndrome; and a CT scan of the cervical spine on 09-13-2013 which showed post-operative changes with disc spacer device at C5-6 and C6-7 with anterior fixation plates and screws, and no fractures or neural foraminal stenosis at any levels. The treatment plan included the continuation with the same medications and a

prescription for Norco 10-325mg #120, one every six hours as needed for pain for the low back, Terocin patches #30, on daily, Genicin 500mg #90, one three times a day, and Flurbiprofen (NAP) cream-LA 180 grams. The injured worker's status was indicated as working. It was noted that the injured worker was retiring on 10-01-2015. The request for authorization was dated 08-13-2015. The treating physician requested Norco 10-235mg #120 (prescription: 09-07-2015), Terocin patches #30, Genicin 500mg #90, and Flurbiprofen (NAP) cream 180 grams #1. On 08-20-2015, Utilization Review (UR) non-certified the request for Norco 10-235mg #120 (prescription: 09-07-2015), Terocin patches #30, Genicin 500mg #90, and Flurbiprofen (NAP) cream 180 grams #1.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Norco 10/235mg (Rx: 09/07/15), QTY: 120: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

**Decision rationale:** The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. In this case, there is documentation of pain and functional improvement seen with the MED being below the advised level of 120. At issue is the quantity requested which is beyond what would be advised without screening for side-effects. As such, the request is not medically necessary.

**Terocin patches, QTY: 30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** The request is for the use of a compounded medication for topical use to aid in pain relief. These products contain multiple ingredients which each have specific properties and mechanisms of action. The MTUS guidelines state the following: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, the compounded topical treatment contains an NSAID. Qualifying factors for this product is indicated by the following per the guidelines: 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. 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. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. In this case, as stated above, the patient would not qualify for the use of a topical NSAID. This is based on the diagnosis and treatment duration. As such, the request is not medically necessary.

**Genicin 500mg, QTY: 90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Glucosamine (and Chondroitin Sulfate).

**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. In this case, the use of glucosamine is not indicated. The patient does not meet the diagnostic criteria set for use. This is secondary to poor high-grade clinical evidence of efficacy for the patient's condition. As such, the request is not medically necessary.

**Flurbi(NAP) cream 180gm, QTY: 1:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** The request is for the use of a topical NSAID for pain relief. There are specific criteria require for use based on the guidelines. The MTUS states the following: 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. 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. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. In this case, as indicated above, the patient would not qualify for the use of this medication based on the treatment duration. As such, the request is not medically necessary.