

<b>Case Number:</b>	CM14-0101415		
<b>Date Assigned:</b>	07/30/2014	<b>Date of Injury:</b>	08/15/2011
<b>Decision Date:</b>	12/04/2014	<b>UR Denial Date:</b>	06/05/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/01/2014

### 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 Anesthesiology, has a subspecialty in Pain Medicine and is licensed to practice in Connecticut. 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:

After careful review of the medical records, this is a 45-year-old female with complaints of low back and left lower extremity pain. The date of injury is 08/15/11 and the mechanism of injury was when she tried to break a fall with her left foot and felt her knee pop as she put all her weight on her left leg. At the time of request for CM3-Ketoprofen 20%, there are subjective (low back pain rated at 6-7/10 and left lower extremity symptoms including aching and burning to her knee; her knee pain can get severe sometimes.) and objective (tenderness over the left lower lumbar facet region, lumbar extension at 5 degrees with pain, positive facet challenge on the left, decreased extensor hallucis longus, inversion and eversion 5-/5 on the left, and negative SLR bilaterally with back pain. Clean, dry and intact left knee portal sites with no signs of infection.) findings, imaging/other findings (L-spine MRI dated 08/11/2012 revealed DDD with facet arthropathy, moderate canal stenosis at L4-5, and L4-5 mild caudal left and L5-S1 mild left caudal neural foraminal narrowing. Left knee MRI dated 08/18/14 revealed complex tear posterior horn to body and anterior horn medial meniscus with medial subluxation of meniscal tissue and medial compartment degenerative change with tibial collateral ligament bursitis and grade 1 medial collateral ligament sprain and with medial femoral condylar osteochondral lesion or focus of osteonecrosis, mild patellar chondral thinning, and prepatellar soft tissue edema with moderate joint effusion and synovitis.), current medications (tramadol and ketoprofen cream.), diagnoses (facet arthropathy of L-spine and disc herniations of L-spine.), and treatment to date (left knee arthroscopic surgery on 02/10/14; Norco, PT, and chiropractic treatment with benefit; lumbar ESI on 03/06/13 with minimal benefit, tramadol and ketoprofen cream with pain relief, improvement in activity level and no side effects; and oral NSAIDs caused GI upset. 05/05/14 report indicated to limit pain medications because of the elevated liver enzymes.) The request for CM3-Ketoprofen 20% was denied on 06/05/14.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**CM3-Ketoprofen 20%:** 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.

**Decision rationale:** According to the CA MTUS guidelines, topical analgesics are an option with specific indications, many agents are compounded as monotherapy or in combination for pain control. Regarding Non-steroidal anti-inflammatory agents; 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. When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. Ketoprofen is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. (Diaz, 2006) (Hindsen, 2006) Absorption of the drug depends on the base it is delivered in. (Gurol, 1996). Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. The only NSAID that is FDA approved for topical application is diclofenac (Voltaren 1% Gel). Clinical trial data suggest that diclofenac sodium gel (the first topical NSAID approved in the US) provides clinically meaningful analgesia in OA patients with a low incidence of systemic adverse events. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the medical necessity of this compounded topical product is not established.