

<b>Case Number:</b>	CM14-0106648		
<b>Date Assigned:</b>	07/30/2014	<b>Date of Injury:</b>	01/19/1999
<b>Decision Date:</b>	08/29/2014	<b>UR Denial Date:</b>	06/13/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/09/2014

### 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 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 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 injured patient is a 67-year-old-female sustained industrial injury on 01/19/1999. The patient complains of occasional neck pain, rated 2/10. She complains of constant low back pain, rated 4/10, with radiation to the left lower extremity. She report of intermittent left shoulder pain. She also complains of clavicle and left wrist/hand pain. Patient reports of constant bilateral knee pain rated 4/10 on the right and rated 3/10 on the left. She is a status post left shoulder arthroscopy. She is attending physical therapy and has had four visits. Her ranges of motion and strengths are improving but she has residuals. Examination of the left knee reveals severe patellofemoral grind. There is medial and lateral joint line tenderness. Examination of the right knee is persistent to patellofemoral grind. There is positive effusion. There is medial and lateral joint line tenderness. Diagnoses are chronic low back pain, status post anterior cervical decompression and fusion, status post bilateral shoulder arthroscopy, left shoulder impingement, rule out internal derangement, right knee internal derangement, chondromalacia patella with persistent symptoms, moderate left greater than right carpal tunnel syndrome, mild bilateral distal ulnar neuropathy, bilateral sacroiliitis with acute flare-up, sciatica, bilateral (B/L) carpal tunnel release and ulnar nerve release, right hand, and status post left foot surgery. The UR determination request is for Flubiprofen 20% cream 120mg; Ketoprofen 20% and Ketamine 10% cream 120gm; Gabapentin 10% + Cyclobenzaprine 10% with 0.375% Capsaicin cream 120gm; post-op physical therapy eight to twelve (8-12) were previously denied.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flurbiprofen 20% cream 120 mg: Upheld**

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

**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. 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 osteoarthritis (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, this compounded topical product is not medically necessary.

**Ketoprofen 20% and Ketamine 10% cream 120 mg: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs and Topical Analgesics Page(s): 111-113.

**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: This agent 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 osteoarthritis (OA) patients with a low incidence of systemic adverse events. Ketamine is currently under study and is only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted. Topical ketamine has only been studied for use in non-controlled studies for complex regional pain syndrome (CRPS) type I and post-herpetic neuralgia and both have shown encouraging results. 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.

**Gabapentin 10% and Cyclobenzaprine 10% with 0.375% Capsaicin cream 120 gm:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs, Ketamine, Capsaicin.

**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. There is little to no research to support the use of many of these agents. According to the guidelines, Gabapentin is not recommended for topical application. There is no peer-reviewed literature to support use. According to the CA MTUS guidelines, muscle relaxants, such as cyclobenzaprine, are not recommended in topical formulation. Per the guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the request is not medically necessary.

**Post op physical therapy, eight to twelve (8-12) additional visits for the left shoulder:**  
Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Physical Medicine. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**Decision rationale:** As per CA MTUS guidelines, physical medicine is based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range of motion, and can alleviate discomfort. Official Disability Guidelines (ODG) for shoulder impingement syndrome, allow 10 physical therapy visits over 8

weeks, post arthroscopy 24 visits over 14 weeks, post-surgery 30 visits over 18 weeks. CA MTUS - Physical Medicine; allows for fading of treatment frequency (from up to 3 visits per week to 1 or less), plus active self-directed home physical medicine. In this case, the injured worker has received unknown number of physical therapy visits; additional physical therapy visits will exceed the allowed number of physical therapy visits per guidelines recommendation. Furthermore, there is no documentation of any significant improvement in the objective measurements such as pain level, range of motion (ROM) or strength. This injured worker should have been well versed in home exercise program by now, to address residual complaints, and maintain functional levels. In addition, there is no evidence of new injuries or revision of surgery to necessitate additional physical therapy. Therefore, the request is considered not medically necessary.