

<b>Case Number:</b>	CM15-0026507		
<b>Date Assigned:</b>	02/20/2015	<b>Date of Injury:</b>	02/04/2009
<b>Decision Date:</b>	04/06/2015	<b>UR Denial Date:</b>	01/13/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/11/2015

### 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: Physical Medicine & Rehabilitation

### 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 54-year-old male, with a reported date of injury of 02/04/2009. The diagnoses include herniated nucleus pulposus, spondylosis, disc height collapse, and stenosis at L5-S1; spondylolisthesis at L5-S1; left-sided foraminal stenosis at L5-S1; status post anterior cervical decompression and fusion at C3-C6; status post fusion at C3-C6 with right upper extremity radiculopathy, exostosis and extra heterotopic ossification; and protrusion with acute radiculopathy of the left lower extremity. Treatments have included an MRI of the cervical spine on 10/08/2014, and oral medications. The progress report dated 12/23/2014 indicates that the injured worker continued to have constant neck pain, with radiation into the right shoulder down into the right arm. He rated the pain 6 out of 10. The injured worker also complained of right shoulder pain, and constant low back pain, with radiation into the left lower extremity with associated numbness. The low back pain was rated 7 out of 10. The objective findings include cervical range of motion at 50%, positive sciatic notch tenderness on the left lumbar spine, positive straight leg raise test, and tension signs in the supine and the seated positions. The treating physician requested Ketoprofen 20% plus Ketamine 10% cream 120 grams and Cyclobenzaprine 10% with 0.375% Capsaicin Cream 120 grams to allow an alternative when oral medications are not well tolerated. On 01/13/2015, Utilization Review (UR) denied the request for Ketoprofen 20% plus Ketamine 10% cream 120 grams and Cyclobenzaprine 10% with 0.375% Capsaicin Cream 120 grams. The UR physician noted that the guidelines do not support compounded medications including Ketoprofen, lidocaine, capsaicin, and other muscle relaxants for topical applications. The MTUS Chronic Pain Guidelines were cited.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Ketoprofen 20% + Ketamine 10% Cream 120gm:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111, 112-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesic, Ketamine Page(s): 111-113, 56.

**Decision rationale:** The patient was injured on 02/04/09 and presents with right shoulder pain, low back pain with radiation into the left lower extremity, and constant neck pain with radiation into the right shoulder and down into the right arm. The request is for KETOPROFEN 20% KETAMINE 10% CREAM 120 GM. The RFA is dated 12/23/14 and the patient is to "remain off work until TTD." The patient has been using this topical cream since 11/21/14. The MTUS guidelines page 111 on topical analgesics states that it is largely experimental in use with few randomized controlled trials to determine efficacy or safety. It is primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. MTUS further states, "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." MTUS page 111 states "Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis." MTUS Guidelines page 56, chronic pain medical treatment guidelines for ketamine states, "Not recommended. There is insufficient evidence to support the use of ketamine for the treatment of chronic pain." MTUS page 113 also has the following regarding ketamine, "Under study: Only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment have been exhausted. Topical ketamine has only been studied for use in non-controlled studies for CRPS 1 and post-herpetic neuralgia, and both have shown encouraging results." The patient has a 50% cervical range of motion, positive sciatic notch tenderness on the left lumbar spine, positive straight leg raise test, and tension signs in the supine and the seated positions. The patient is diagnosed with herniated nucleus pulposus, spondylosis, disc height collapse, and stenosis at L5-S1; spondylolisthesis at L5-S1; left-sided foraminal stenosis at L5-S1; status post anterior cervical decompression and fusion at C3-C6; status post fusion at C3-C6 with right upper extremity radiculopathy, exostosis and extra heterotopic ossification; and protrusion with acute radiculopathy of the left lower extremity. Regarding Ketamine, the patient has not been diagnosed with CRPS or post-herpetic neuralgia, and ketamine has not been shown in any studies to provide functional improvement for other neuropathic pain. Furthermore, Ketoprofen is not approved for topical formulation per MTUS. The requested Ketoprofen/Ketamine compounded cream IS NOT medically necessary.

**Cyclobenzaprine 10% with .375% Capsaicin Cream 120gm:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111, 112-113.

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

**Decision rationale:** The patient was injured on 02/04/09 and presents with right shoulder pain, low back pain with radiation into the left lower extremity, and constant neck pain with radiation into the right shoulder and down into the right arm. The request is for CYCLOBENZAPRINE 10% W/ 0.375%. The RFA is dated 12/23/14 and the patient is to "remain off work until TTD." The patient has been using this topical cream since 11/21/14. MTUS has the following regarding topical creams (page 111, chronic pain section): "Topical Analgesics: Non-steroidal anti-inflammatory agents (NSAIDs): 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." Cyclobenzaprine is a muscle relaxant and is not supported for any topical formulation. MTUS Guidelines allows capsaicin for chronic pain condition such as fibromyalgia, osteoarthritis, and nonspecific low back pain. However, MTUS Guidelines consider doses that are higher than 0.025% to be experimental particularly at high doses. The patient has a 50% cervical range of motion, positive sciatic notch tenderness on the left lumbar spine, positive straight leg raise test, and tension signs in the supine and the seated positions. The patient is diagnosed with herniated nucleus pulposus, spondylosis, disc height collapse, and stenosis at L5-S1; spondylolisthesis at L5-S1; left-sided foraminal stenosis at L5-S1; status post anterior cervical decompression and fusion at C3-C6; status post fusion at C3-C6 with right upper extremity radiculopathy, exostosis and extra heterotopic ossification; and protrusion with acute radiculopathy of the left lower extremity. In this case, the requested compounded cream contains 0.375% Capsaicin which is not supported by MTUS Guidelines. Furthermore, Cyclobenzaprine in a topical formulation is not supported. The requested Cyclobenzaprine/Capsaicin cream IS NOT medically necessary.