

<b>Case Number:</b>	CM15-0095541		
<b>Date Assigned:</b>	05/22/2015	<b>Date of Injury:</b>	07/09/2002
<b>Decision Date:</b>	07/03/2015	<b>UR Denial Date:</b>	05/06/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/18/2015

### 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:

This 60 year old male sustained an industrial injury to bilateral wrists, bilateral elbows, bilateral knees, neck and back on 7/9/02. Recent treatment included transcutaneous electrical nerve stimulator unit, wrist braces and medications. In the most recent PR-2 submitted for review, dated 11/26/14, the injured worker complained of pain to the cervical spine, lumbar spine, bilateral patella, bilateral wrists and bilateral elbows rated 8/10 on the visual analog scale without medications and 6/10 with medications. The injured worker also complained of headaches and arm cramps. The injured worker reported that medications offer some relief. Physical exam was remarkable for tenderness to palpation to the cervical spine, lumbar spine, cervical facets and lumbar facets with limited range of motion due to pain as well as limited range of motion to bilateral wrists and left shoulder due to pain. The physician noted that the injured worker had failed multiple conservative therapies and various medications trials without benefit. The injured worker was recently seen in the Emergency Department for an episode of lightheadedness, passing out and slurred speech. Stroke was ruled out. The physician stated that the injured worker was stable on the current medication regimen allowing for improved activities of daily living. There was no evidence of aberrant drug taking. Current diagnoses included chronic pain syndrome, shoulder joint pain, upper arm joint pain, lumbar post laminectomy syndrome, neck pain, cervical spine radiculopathy, low back pain, lumbar radiculopathy, muscle spasms, anxiety and migraines. The treatment plan included discontinuing Morphine Sulfate IR, reducing the dosage of Fentanyl patch, reducing the dosage of Norco, discontinuing Valium, continuing Baclofen, Colace and Ambien and continuing with activity as tolerated.

## IMR ISSUES, DECISIONS AND RATIONALES

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

### **Retrospective Flurbiprofen/Lidocaine/Versapro Base (DOS 3/6/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Topical flurbiprofen/capsaicin.

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

**Decision rationale:** The patient was injured on 07/09/02 and presents with pain in the cervical region, lumbar region, both patella, both wrists, and both elbows. The retrospective request is for FLURBIPROFEN/ LIDOCAINE/ VERSAPRO BASE (DOS: 03/06/15). There is no RFA provided and the patient is on temporary total disability. 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. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain." Flurbiprofen, an NSAID, is indicated for peripheral joint arthritis/tendinitis. The patient has a limited cervical/lumbar spine range of motion, cervical/lumbar paraspinal tenderness, cervical facet tenderness at C5-T1, lumbar facet tenderness at L4-S1, a limited bilateral wrist range of motion, and a limited left shoulder range of motion. The patient is diagnosed with chronic pain syndrome, shoulder joint pain, upper arm joint pain, lumbar post laminectomy syndrome, neck pain, cervical spine radiculopathy, low back pain, lumbar radiculopathy, muscle spasms, anxiety, and migraines. MTUS Guidelines page 111 do not recommend a compounded product if one of the compounds are not indicated for use. In this case, Lidocaine (in a non-patch form) is not indicated for use as a topical formulation. The requested topical cream IS NOT medically necessary.

### **Retrospective Gabapentin/Amitriptyline/Capsaicin/Versapro base (DOS 3/6/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Topical flurbiprofen/capsaicin.

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

**Decision rationale:** The patient was injured on 07/09/02 and presents with pain in the cervical region, lumbar region, both patella, both wrists, and both elbows. The retrospective request is for GABAPENTIN/ AMITRIPTYLINE/ CAPSAICIN/ VERSAPRO BASE (DOS: 03/06/15). There

is no RFA provided and the patient is on temporary total disability. MTUS guidelines has the following regarding topical creams (p 111, chronic pain section): "Topical analgesics are largely experimental and used with few randomized controlled trials to determine efficacy or safety. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. 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. Gabapentin: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. MTUS continues to state that many agents are compounded for pain control including antidepressants and that there is little to no research to support their use. There is currently one Phase III study of baclofen-amitriptyline-ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. There is no peer review literature to support the use of topical baclofen. The patient has a limited cervical/lumbar spine range of motion, cervical/lumbar paraspinal tenderness, cervical facet tenderness at C5-T1, lumbar facet tenderness at L4-S1, a limited bilateral wrist range of motion, and a limited left shoulder range of motion. The patient is diagnosed with chronic pain syndrome, shoulder joint pain, upper arm joint pain, lumbar post laminectomy syndrome, neck pain, cervical spine radiculopathy, low back pain, lumbar radiculopathy, muscle spasms, anxiety, and migraines. Amitriptyline is a tricyclic antidepressant. MTUS specifically states that anti-depressants such as Amitriptyline are not recommended and this ingredient has not been tested for transdermal use with any efficacy. The requested compounded cream also contains Gabapentin which is not indicated by guidelines. MTUS states, any compounded product that contains at least one (or drug class) that is not recommended is not recommended." Neither Amitriptyline nor Gabapentin are indicated for topical cream. The requested compounded cream IS NOT medically necessary.

**Retrospective Cyclobenzaprine/Lidocaine/Versapro base (DOS 3/6/15): Upheld**

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

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

**Decision rationale:** The patient was injured on 07/09/02 and presents with pain in the cervical region, lumbar region, both patella, both wrists, and both elbows. The retrospective request is for CYCLOBENZAPRINE/ LIDOCAINE/ VERSAPRO BASE (DOS: 03/06/15). There is no RFA provided and the patient is on temporary total disability. MTUS Guidelines has the following regarding topical creams (page 111, chronic pain section): topical analgesics: Nonsteroidal anti-inflammatory agents (NSAIDs): Efficacy in clinical trials for this treatment modality has been inconsistent and most of these 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. Topical lidocaine, in the formulation of a dermal patch (Lidoderm), has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially-approved topical formulations of lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain. Cyclobenzaprine is a muscle

relaxant and is not supported for any topical formulation. The patient has a limited cervical/lumbar spine range of motion, cervical/lumbar paraspinal tenderness, cervical facet tenderness at C5-T1, lumbar facet tenderness at L4-S1, a limited bilateral wrist range of motion, and a limited left shoulder range of motion. The patient is diagnosed with chronic pain syndrome, shoulder joint pain, upper arm joint pain, lumbar post laminectomy syndrome, neck pain, cervical spine radiculopathy, low back pain, lumbar radiculopathy, muscle spasms, anxiety, and migraines. MTUS Guidelines page 111 do not recommend a compounded product if one of the compounds are not indicated for use. In this case, neither Cyclobenzaprine nor Lidocaine (in a non-patch form) are indicated for use as a topical formulation. Therefore, the requested compounded medication IS NOT medically necessary.

**Retrospective Zolpidem 10mg #30 (DOS 3/6/15): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Ambien (Zolpidem), Medscape 2009.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disability guidelines mental illness and stress chapter, zolpidem (Ambien).

**Decision rationale:** The patient was injured on 07/09/02 and presents with pain in the cervical region, lumbar region, both patella, both wrists, and both elbows. The retrospective request is for ZOLPIDEM 10 MG #30 (DOS: 03/06/15). There is no RFA provided and the patient is on temporary total disability. MTUS and ACOEM Guidelines are silent with regard to his request. However, ODG Guidelines, mental illness and stress chapter, zolpidem (Ambien) states, Zolpidem (Ambien, generic available, Ambien CR) is indicated for short term use of insomnia with difficulty of sleep onset (7-10 days). Ambien CR is indicated for treatment of insomnia with difficulty of sleep onset and/or sleep maintenance. Long term studies have found Ambien CR to be effective for up to 24 weeks in adults. The patient has a limited cervical/lumbar spine range of motion, cervical/lumbar paraspinal tenderness, cervical facet tenderness at C5-T1, lumbar facet tenderness at L4-S1, a limited bilateral wrist range of motion, and a limited left shoulder range of motion. The patient is diagnosed with chronic pain syndrome, shoulder joint pain, upper arm joint pain, lumbar post laminectomy syndrome, neck pain, cervical spine radiculopathy, low back pain, lumbar radiculopathy, muscle spasms, anxiety, and migraines. The 11/26/14 report states that the patient has anxiety with insomnia. The patient has been taking Zolpidem as early as 11/26/14. ODG Guidelines support the use of Ambien for 7 to 10 days for insomnia. However, the patient has been taking this medication since 11/26/14 which exceeds the 7 to 10 day limit indicated by ODG Guidelines. In this case, this medication has been used on a long-term basis which is not recommended by ODG Guidelines. Therefore, the requested Zolpidem IS NOT medically necessary.