

<b>Case Number:</b>	CM15-0090889		
<b>Date Assigned:</b>	05/15/2015	<b>Date of Injury:</b>	11/17/2005
<b>Decision Date:</b>	06/22/2015	<b>UR Denial Date:</b>	04/10/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/11/2015

### 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: New York, Tennessee  
 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 69-year-old male who reported an industrial injury on 11/17/2005. His diagnoses, and/or impressions, are noted to include cervical disc disease with radiculopathy, exacerbation; thoracic musculoligamentous strain/sprain, exacerbation; lumbar spine spondylosis with history of lumbar spine disc herniation and radiculopathy, exacerbation; bilateral shoulder strain/sprain and tendinitis; left shoulder rotator cuff tear; bilateral hip strain/sprain; right knee internal derangement with anterior cruciate ligament tear and advanced/end-stage osteoarthritis/tendinosis. No current imaging studies are noted. His treatments have included physical therapy; rest from work; medication management and toxicology screenings. The progress notes of 3/13/2015 reported improvement in, and mild pain, in his neck that radiated into the bilateral Cervical and Lumbar dermatomes, upper-back, bilateral shoulders, bilateral hips and into the right knee. The objective findings were noted to include tenderness, restricted range-of-motion, and positive compression test in the cervical spine; tenderness with restricted range-of-motion and spasms in the thoracic spine; tenderness with restricted range-of-motion and positive bilateral straight leg raise test in the lumbar spine; tenderness with restricted range-of-motion and positive impingement and supra-spinatus tests in the bilateral shoulders; tenderness in the bilateral hips and knees; and the use of a cane to ambulate. The physician's requests for treatments were noted to include Flurbi (nap) cream & Gabacyclotram cream to minimize possible neurovascular complications associated with narcotic medications and gastrointestinal bleeding; extra-corporeal shock-wave therapy for the right knee; and a urine toxicology screening.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Flurbi (Nap) cream-LA (Flurbiprofen 20%/Lidocaine 5%/ Amitriptyline 5%) 180 grams  
2- 3 times per day (prescribed 3/15/15): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 13-15, 111-112.

**Decision rationale:** This medication is a compounded topical analgesic containing flurbiprofen, lidocaine, and amitriptyline. Topical analgesics are recommended for neuropathic pain when anticonvulsants and antidepressants have failed. Compounded topical analgesics are commonly prescribed and there is little to no research to support the use of these compounds. Furthermore, the guidelines state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Flurbiprofen is a non-steroidal anti-inflammatory drug (NSAID). Flurbiprofen is recommended as an oral agent for the treatment of osteoarthritis and the treatment of mild to moderate pain. It is not recommended as a topical preparation. Lidocaine is recommended for localized peripheral pain after the evidence of a trial for first-line therapy, such as an antidepressant or antiepileptic drug. It is only FDA approved for the treatment of post-herpetic neuralgia. The guidelines state that further research is needed to recommend this treatment for chronic neuropathic pain. In this case, the patient has no diagnosis of post-herpetic neuralgia. Lidocaine is not recommended. Amitriptyline is a tricyclic antidepressant. Tricyclics are generally considered a first-line agent for neuropathic pain, unless they are ineffective, poorly tolerated, or contraindicated. Indications in controlled trials have shown effectiveness in treating central post-stroke pain, post-herpetic neuralgia, painful diabetic and non-diabetic polyneuropathy, and post-mastectomy pain. Negative results were found for spinal cord pain and phantom-limb pain, but this may have been due to study design. Tricyclics have not demonstrated significance in randomized-control trials in treating HIV neuropathy, spinal cord injury, cisplatin neuropathy, neuropathic cancer pain, phantom limb pain or chronic lumbar root pain. Caution is required because tricyclics have a low threshold for toxicity, and tricyclic antidepressant overdose is a significant cause of fatal drug poisoning due to their cardiovascular and neurological effects. Analgesia generally occurs within a few days to a week, whereas antidepressant effect takes longer to occur. It is not recommended as a topical preparation. This medication contains drugs that are not recommended. Therefore, the medication cannot be recommended. The request is not medically necessary.

**Gabaclotram (Gabapentin 10%/Cyclobenzaprine 6%/Tramadol 10%) 180 grams  
(prescribed 3/13/15): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 74-96, 111-112.

**Decision rationale:** This medication is a compounded topical analgesic containing gabapentin, cyclobenzaprine, and tramadol. Topical analgesics are recommended for neuropathic pain when anticonvulsants and antidepressants have failed. Compounded topical analgesics are commonly prescribed and there is little to no research to support the use of these compounds. Furthermore, the guidelines state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Gabapentin is not recommended. There is no peer-reviewed literature to support use. Cyclobenzaprine is a muscle relaxant. There is no evidence for use of this muscle relaxant as a topical product. Tramadol is a synthetic opioid affecting the central nervous system. It has several side effects, which include increasing the risk of seizure in patients taking SSRIs, TCAs and other opioids. It is not recommended as a topical preparation. This medication contains drugs that are not recommended. Therefore, the medication cannot be recommended. The request is not medically necessary.

**Physical therapy on hold:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 98-99.

**Decision rationale:** Chronic Pain Medical Treatment Guidelines state that there is no high-grade scientific evidence to support the effectiveness or ineffectiveness of passive physical modalities such as traction, heat/cold applications, massage, diathermy, TENS units, ultrasound, laser treatment, or biofeedback. They can provide short-term relief during the early phases of treatment. Active treatment is associated with better outcomes and can be managed as a home exercise program with supervision. ODG states that physical therapy is more effective in short-term follow up. Patients should be formally assessed after a "six-visit clinical trial" to see if the patient is moving in a positive direction, no direction, or a negative direction (prior to continuing with the physical therapy). When treatment duration and/or number of visits exceed the guideline, exceptional factors should be noted. Recommended number of visits for myalgia and myositis is 9-10 visits over 8 weeks; and for neuralgia, neuritis, and radiculitis is 8-10 visits over 4 weeks. In this case, there is documentation that prior treatment with physical therapy has decreased pain. There is no documentation of objective evidence of functional benefit. Physical therapy is on hold and is not indicated at this time. The request is not medically necessary.