

<b>Case Number:</b>	CM14-0139699		
<b>Date Assigned:</b>	09/05/2014	<b>Date of Injury:</b>	11/30/2010
<b>Decision Date:</b>	10/09/2014	<b>UR Denial Date:</b>	08/08/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/28/2014

### 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 and Rehabilitation and is licensed to practice in California and Washington. 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 worker is a 56-year-old male who reported an injury on 11/30/2010 reportedly while at work he bent down to pick up a tube weighing approximately 30 pounds that was in a ditch. As he tried to move the tube, water came out of the tube, causing the weight to shift in the tube. He stated he experienced sudden, sharp pain in his low back and a pulling sensation in his bilateral shoulders. The injured worker's treatment history included x-rays, physical therapy, medications, and MRI studies. The injured worker was evaluated on 08/29/2014 and it was documented that the injured worker complained of low back pain that was rated at 5/10 to 6/10 that was throbbing and burning in nature. His pain was continuous throughout the entire day. The objective findings of the bilateral were flexion was 180 degrees, extension was 50 degrees, adduction was 40 degrees, abduction was 170 degrees, internal rotation was 80 degrees, and external rotation was 90 degrees. For the elbows, pronation was 80 degrees and supination was 80 degrees. For the lumbar spine, flexion was to ankles, extension was 20 degrees, and lateral flexion was 25 degrees bilaterally. Medications included Ultra Flex-G cream, Gabapentin 10%, Cyclobenzaprine 6%, Tramadol 10%. Diagnoses included mechanical discogenic low back pain, traumatic compression fracture of superior endplate, L3-4 and L4-5 degenerative disc disease, T/S myoligamentous sprain/strain, bilateral shoulder impingement syndrome, and bilateral shoulder tendinosis. The Request for Authorization dated 09/01/2014 was for topical cream.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**EnovaRx-cyclobenzaprine cream 2%:** Upheld

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

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

**Decision rationale:** The request for Enova-RX cyclobenzaprine is not medically necessary. Chronic Pain Medical Treatment Guidelines state that topical analgesics. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. Gabapentin: Not recommended. There is no peer-reviewed literature to support use. Other antiepilepsy drugs: There is no evidence for use of any other ant epilepsy drug as a topical product. Lidocaine Indication: Neuropathic pain Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as Gabapentin or Lyrica). 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. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. The provider failed to indicate where topical cream will be applied and quantity of requested medication. As, such the request is not medically necessary.

**EnovaRx-ibuprofen cream 10%:** Upheld

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

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

**Decision rationale:** The request for Enova RX- Ibuprofen Cream 10% is not medically necessary. Chronic Pain Medical Treatment Guidelines states that topical analgesics. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack

of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). There is little to no research to support the use of many of these agents. 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. 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. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. The documents submitted review failed to indicate outcome measurements of pain medication management. Additionally, the guidelines do not recommend topical NSAIDs to be no more than 4-12 weeks duration could not be established. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. Gabapentin: Not recommended. There is no peer-reviewed literature to support use. Other ant epilepsy drugs: There is no evidence for use of any other ant epilepsy drug as a topical product. Lidocaine Indication: Neuropathic pain Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as Gabapentin or Lyrica). 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. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. The provider failed to indicate where topical cream will be applied and quantity of requested medication. As, such the request is not medically necessary.