

<b>Case Number:</b>	CM14-0185446		
<b>Date Assigned:</b>	11/13/2014	<b>Date of Injury:</b>	08/23/2014
<b>Decision Date:</b>	12/16/2014	<b>UR Denial Date:</b>	11/03/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/06/2014

### 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, has a subspecialty in Spinal Cord Injury and is licensed to practice in New York. 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 51-year-old female who reported an injury on 08/23/2014. The mechanism of injury was a fall. The injured worker's diagnoses included cervical spine sprain/strain, headaches, low back pain, and right foot/toe pain. The injured worker's past treatments included splinting and medications. The injured worker's diagnostic testing included MRIs of multiple body parts, performed on 10/06/2014. An MRI of the cervical spine revealed disc desiccation noted at the C5-6 and C6-7 levels. An MRI of the right ankle was noted to reveal small vasculature malformation in the posterior calf region and no other abnormalities noted. An MRI of the left wrist was noted to reveal small distal radioulnar joint effusion. An MRI of the lumbar spine was noted to reveal grade 1 retrolisthesis of L5 over S1, disc desiccation noted at the L3-4, L4-5, and L5-S1 levels, and reduced intervertebral disc height at the L5-S1 level. There was bilateral neural foraminal stenosis at the L4-5 and L5-S1 levels. There were no relevant surgeries included in the documentation. On 09/12/2014, the injured worker complained of headaches, radicular neck pain, radicular low back pain, bilateral wrist pain, and pain in the right ankle, foot, and toes. She rated her pain in all areas as 7/10 on a pain scale. She reported the pain was alleviated with medications, rest, and activity restriction. Upon physical examination, the injured worker was noted with decreased range of motion of the cervical spine and lumbar spine. Sensation to pinprick and light touch was slightly diminished over the C5, C6, C7, C8, and T1 dermatomes in the bilateral upper extremities. Motor strength was 4/5 in all represented muscle groups in the bilateral upper extremities. She was noted with slightly decreased sensation to pinprick and light touch at the L4, L5, and S1 dermatomes in the right lower extremity. The injured worker's medications included Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Cyclobenzaprine, and Ketoprofen cream. The request was for 1 container of Cyclobenzaprine 2%/Flurbiprofen 25%, 180 grams and 1 container of

Cyclobenzaprine 2%/Gabapentin 15%/Amitriptyline 10%, 180 grams. The rationale for the request was not provided. The Request for Authorization form was not submitted for review.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **1 Container of Cyclobenzaprine 2% and Flurbiprofen 25%, 180 grams: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics, Cyclobenzaprine Page(s): 41, 111-113.

**Decision rationale:** The request for 1 container of Cyclobenzaprine 2% and Flurbiprofen 25% with 180 grams is not medically necessary. According to the California MTUS Guidelines, topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. 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. Any compounded product that contains at least 1 drug (or drug class) that is not recommended, is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful the specific therapeutic goal required. The efficacy in clinical trials for topical NSAIDs have 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 diminishing effect over another 2 week period. A study revealed 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. There is little evidence to utilize topical NSAIDs for the treatment of osteoarthritis of the spine, hip, or shoulder. Regarding Cyclobenzaprine, the guidelines do not recommend the addition of Cyclobenzaprine to other agents. The injured worker complained of pain in multiple body parts. However, a complete and thorough pain assessment was not included in the documentation. A pain assessment should include a current quantified pain; the least reported pain over the period since last assessment; the intensity of pain after taking the medication; and how long pain relief lasts. In the absence of documentation with evidence of a complete and thorough pain assessment, and as the guidelines do not recommend the addition of Cyclobenzaprine to other agents, the request is not supported. Additionally, as the request was written, there was no frequency provided. As such, the request is not medically necessary.

#### **1 Container of Cyclobenzaprine 2%, Gabapentin 15% and Amitriptyline 10% 180 Grams: Upheld**

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

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

**Decision rationale:** The request for 1 container of Cyclobenzaprine 2%, Gabapentin 15% and Amitriptyline 10% 180 Grams is not medically necessary. According to the California MTUS Guidelines, topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. 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. Any compounded product that contains at least 1 drug (or drug class) that is not recommended, is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful the specific therapeutic goal required. The efficacy in clinical trials for topical NSAIDs have 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 diminishing effect over another 2 week period. A study revealed 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. There is little evidence to utilize topical NSAIDs for the treatment of osteoarthritis of the spine, hip, or shoulder. Regarding Cyclobenzaprine, the guidelines do not recommend the addition of Cyclobenzaprine to other agents. The injured worker complained of pain in multiple body parts. However, a complete and thorough pain assessment was not included in the documentation. A pain assessment should include a current quantified pain; the least reported pain over the period since last assessment; the intensity of pain after taking the medication; and how long pain relief lasts. Furthermore, the guidelines do not recommend the use of Gabapentin in a topical agent. There is no peer reviewed literature to support use. Any compounded product that contains at least 1 drug (or drug class) that is not recommended, is not recommended. In the absence of documentation with evidence of a complete and thorough pain assessment, and as the guidelines do not recommend the addition of Cyclobenzaprine to other agents, the request is not supported. Additionally, as the request was written, there was no frequency provided. As such, the request is not medically necessary.