

<b>Case Number:</b>	CM14-0047169		
<b>Date Assigned:</b>	07/02/2014	<b>Date of Injury:</b>	06/15/2013
<b>Decision Date:</b>	08/28/2014	<b>UR Denial Date:</b>	03/25/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/15/2014

### 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 Anesthesiology, has a subspecialty in Pain Medicine and is licensed to practice in Florida. 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 55-year-old female who reported an injury on 06/15/2013 due to a fall that caused her to land on her right side injuring her wrist, hand, elbow and shoulder. The injured worker had a history of back pain that radiated to the bilateral lower extremities that included numbness, tingling and weakness. The injured worker had a diagnosis of pain in the limbs, neck pain, limb numbness, limb weakness, and paresthesia. The MRI dated 03/08/2014 revealed lumbar lordosis, a large chronic Schmorl's node at the anterior aspect of the superior implant at the L4. The L1-2 through L5-S1 intervertebral discs revealed a reduction in height and T12-L1 focal central anterior disc extrusion. The MRI to the left knee dated 03/13/2014 revealed no abnormalities. Past treatments included physical therapy. The electrodiagnostic findings revealed abnormal severe sensorimotor median neuropathy across bilateral wrists, no evidence of ulnar neuropathy or polyneuropathy. The objective findings dated 02/10/2014 of the extremities demonstrated no abnormalities, muscle strength 5/5 with tenderness to palpation at the bilateral wrists, elbows, and shoulders. Sensation to light touch is grossly intact. The examination of the spine revealed no evidence of abnormalities with no tenderness to palpation at the trapezius or cervical paraspinal muscles. No lumbar spinal examination for review. The medications included Flexeril, Naproxen, and Vicodin. The treatment plan included relieving pain with heat, hot baths, and walking. The request for authorization dated 07/02/2014 was submitted within the documentation. No rationale provided.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**1 month supply of Tramadol (quantity unknown): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Medical food.

**Decision rationale:** The request for 1 month supply of Tramadol (quantity unknown) is not medically necessary. The Official Disability Guidelines recommend Tramadol as a food which is formulated to be consumed or administered eternally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. To be considered the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. See Food labeling; Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrition Content Revision proposed rule (56 FR 60366 at 60377, November 27, 1991). Medical foods are exempted from the labeling requirements for health claims and nutrient content claims under the Nutrition Labeling and Education Act of 1990 (see 21 U.S.C. 343 (q) (5) (A) (IV)). Medical foods do not have to be registered with the FDA. The current available medical food products: Choline: Choline is a precursor of acetylcholine. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. There is inconclusive evidence that this product is indicated for an endurance aid, memory, seizures, and transient ischemic attacks. Side effects of high dose choline include hypotension, acute GI distress, and cholinergic side effects (such as sweating and diarrhea). A fishy odor may occur with use. Per the documentation provided the injured worker did not require oral or tube feeding. The injured worker did not require parenteral nutritional. The request did not address the frequency. As such, the request is not medically necessary.

**1 month supply of Cyclophene (quantity unknown): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** The request for 1 month supply of Cyclophene is not medically necessary. The California MTUS state that topical analgesics are 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. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. Per the guidelines Cyclophene is not recommended. The request did not address the frequency. As such, the request is not medically necessary.

**1 month supply of Ketoprofen Cream (quantity unknown): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** The request for Ketoprofen is not medically necessary. The California/MTUS indicate that Ketoprofen is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis. Absorption of the drug depends on the base it is delivered in. Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. The request did not address the frequency. As such, the request is not medically necessary.

**1 month supply of Terocin Patch (quantity unknown): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, page 111-112 Page(s): 111-112.

**Decision rationale:** The request for 1 month supply of Terocin patch is not medically necessary. The California MTUS Guidelines on topical analgesics state any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended. Topical Lidocaine, in the formulation of a Lidoderm patch, has been designated as an 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. A Terocin patch is a topical analgesic with active ingredients of Lidocaine 4% and Methodyl 4%. The combination of Lidocaine with any other topical medication is not recommended per Guidelines. The request did not address the frequency. As such, the request is not medically necessary.