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| <b>Case Number:</b>   | CM15-0208584 |                              |            |
| <b>Date Assigned:</b> | 10/27/2015   | <b>Date of Injury:</b>       | 10/27/2008 |
| <b>Decision Date:</b> | 12/10/2015   | <b>UR Denial Date:</b>       | 10/13/2015 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 10/22/2015 |

### 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:

The injured worker is a 49 year old male, who sustained an industrial injury on October 27, 2008. The injured worker was diagnosed as having nerve compression with the left greater than the right, status post lumbar four to five disc compression fusion, and lumbar spine pseudarthrosis at lumbar four to five. Treatment and diagnostic studies to date has included acupuncture, above noted procedure, magnetic resonance imaging of the lumbar spine, at least 10 sessions of physical therapy, medication regimen, and home exercise program. In a progress note dated August 05, 2015 the treating physician reports complaints of pain to the low back that radiates to the right lower extremity. Examination performed on August 05, 2015 was revealing for tenderness and spasms to the lumbar paraspinal muscles, positive straight leg raises to the bilateral lower extremities, and decreased range of motion to the lumbar spine. The injured worker's medication regimen on August 05, 2015 included Cyclobenzaprine, Methoderm, and Omeprazole (since at least May of 2015). The injured worker's medication regimen on July 08, 2015 included Omeprazole and Cyclobenzaprine. The progress notes from August 05, 2015 and July 08, 2015 did not indicate the injured worker's pain level as rated on a pain scale prior to use of his medication regimen and after use of his medication regimen to indicate the effects with the use of the injured worker's medication regimen. Also, the documentation provided did not indicate if the injured worker experienced any functional improvement with use of his medication regimen. The treating physician requested the compound medication of Gabapentin, Amitriptyline, and Dextromethorphan cream to be applied in a thin layer to affected area 2-3 times a day dispensed on September 03, 2015, but did not indicate the specific reason for the

requested medication. On October 12, 2015 the Utilization Review determined the request for the compound medication of Gabapentin, Amitriptyline, and Dextromethorphan cream to be applied in a thin layer to affected area 2-3 times a day dispensed on September 03, 2015 to be non-certified.

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

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

**Compound Gabapentin/Amitriptyline/Dextromethorphan cream apply thin layer to affected area 2-3 times a day dispensed on 9/03/15: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** The patient was injured on 10/27/08 and presents with low back pain and bilateral lower extremity pain. The request is for compound Gabapentin/Amitriptyline/Dextromethorphan cream apply thin layer to affected area 2-3 times a day dispensed on 9/03/15. There is no RFA provided and the patient's current work status is not provided either. MTUS Guidelines, Topical Analgesics NSAIDs section, page 111 states: "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. 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 is diagnosed with nerve compression with the left greater than the right, status post lumbar four to five disc compression fusion, and lumbar spine pseudarthrosis at lumbar four to five. Treatment to date includes acupuncture, at least 10 sessions of physical therapy, medication regimen, and home exercise program. 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.