

<b>Case Number:</b>	CM14-0179541		
<b>Date Assigned:</b>	11/04/2014	<b>Date of Injury:</b>	11/20/2013
<b>Decision Date:</b>	12/09/2014	<b>UR Denial Date:</b>	09/24/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/29/2014

### 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, has a subspecialty in Pain Medicine and is licensed to practice in California. 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:

This is a 48-year-old male patient who sustained an industrial injury on 11/20/2013 when his forklift trailer. The patient is diagnosed with lumbar sprain/strain, lumbar radiculopathy, shoulder sprain/strain, rotator cuff, and insomnia. The patient has subjective complaints of bilateral low back pain rated at 5-9/10, left shoulder pain rated at 2-5/10, and loss of sleep. Objective findings are noted as tenderness/spasm in the lumbar area, decreased lumbar range of motion, tenderness in the shoulder area, and decreased shoulder range of motion. Lower extremity nerve conduction study performed 04/23/14 was normal. CT of the lumbar spine performed on 04/28/14 revealed anterior osteophytosis of the lumbar vertebrae. Bony hypertrophy of the articular facets at the level of L4-5 and L5-S1. No disc bulge and/or herniation. Previous treatment has included physical therapy, chiropractic, and acupuncture treatment as well as compounded topical creams and opioids. Requests for compounded topical creams containing Cyclobenzaprine 2%, Gabapentin 15%, Amitriptyline 10% 180 gm cream Quantity: 1 and Gabapentin 15%, Amitriptyline 10%, Dextromethorphan 10% 180 gm cream Quantity: 1 were non-certified at utilization review on 09/24/14 with the reviewing physician noting there is no documentation of significant pain reduction in her objective measures of functional restoration noted with the continued use of the requested medications. Topical compounding medication has not been shown to result in superior systemic blood levels versus appropriately use oral medications in FDA for dosages. These medications are largely experimental in use with few randomized controlled trials to determine efficacy or safety.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Cyclobenzaprine 2%, Gabapentin 15%, Amitriptyline 10% 180 gm cream Quantity: 1:**  
Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113. Decision based on Non-MTUS Citation ODG Pain/Compound drugs

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

**Decision rationale:** The CA MTUS states "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...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). (Argoff, 2006) 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." In this case, the requested formulation contains amitriptyline and there is no evidence to support antidepressants in topical application. The requested formulation contains gabapentin, and per CA MTUS, "Gabapentin: Not recommended. There is no peer-reviewed literature to support use." Regarding cyclobenzaprine, guidelines note "Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." As the requested compounded topical cream contains multiple agents not supported by guidelines, the request for Cyclobenzaprine 2%, Gabapentin 15%, Amitriptyline 10% 180 gm cream Quantity: 1 is not medically .

**Gabapentin 15%, Amitriptyline 10%, Dextromethorphan 10% 180 gm cream Quantity: 1:**  
Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics 111-113. Decision based on Non-MTUS Citation ODG Pain/Compound drugs

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

**Decision rationale:** The CA MTUS states "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...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). (Argoff, 2006) 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." In this case, the requested formulation contains amitriptyline and there is no evidence to support antidepressants in topical application. The requested formulation contains gabapentin, and per CA MTUS, "Gabapentin: Not recommended. There is no peer-reviewed literature to support use." There is no evidence to support the use of dextromethorphan in topical application. As the requested compounded topical cream contains multiple agents not supported by guidelines, the request for Gabapentin 15%, Amitriptyline 10%, Dextromethorphan 10% 180 gm cream Quantity: 1 is not medically necessary.