

Case Number:	CM15-0221575		
Date Assigned:	11/17/2015	Date of Injury:	04/06/2014
Decision Date:	12/30/2015	UR Denial Date:	10/20/2015
Priority:	Standard	Application Received:	11/11/2015

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 42-year-old male, who sustained an industrial injury on 4-6-2014. The injured worker is undergoing treatment for low back pain. On 3-5-15, and 6-1-15, he reported back pain with stiffness that had remained unchanged and rated 5-6 out of 10. Objective findings revealed an abdominal hernia in the periumbilical area, thoracic spine with "abnormal findings", lumbar spine with "abnormal findings", tenderness in the paraspinals, and positive bilateral straight leg raise testing, tenderness in the plantar fascia and calcaneal fibular ligament and lateral malleolus. The treatment and diagnostic testing to date has included: medications, urine drug screen (4-9-15, 8-21-15), MRI of lumbar spine (8-25-15), electro diagnostic studies (6-5-15). Medications have included compounded topical creams. Current work status: off work. The request for authorization is for: compounded medications: NPC1 Gabapentin 10 percent-amitriptyline 10 percent-bupivacaine 5 percent CR 210 quantity 210 grams; and MPC1 flurbiprofen 20 percent-baclofen 10 percent-dexamethasone 2 percent CR 210 quantity 210 grams. The UR dated 10-20-2015: non-certified the request for compounded medications: NPC1 Gabapentin 10 percent-amitriptyline 10 percent-bupivacaine 5 percent CR 210 quantity 210 grams; and MPC1 flurbiprofen 20 percent-baclofen 10 percent-dexamethasone 2 percent CR 210 quantity 210 grams.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective; NPCI Gabapentin 10%/Amitriptyline 10%/Bupivacaine 5% CR 210# 210gram, Rx 8/23/15: 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 04/06/14 and presents with pain in his mid back, lowers back, and left leg. The retrospective request is for NPCI GABAPENTIN 10%/AMITRYPTILINE 10%/BUPIVACAINE 5% CR 210 # 210 GRAM, RX 8/23/15. There is no RFA provided and the patient is not currently working. MTUS guidelines have the following regarding topical creams (p111, chronic pain section): "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. Baclofen: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. 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 low back pain. 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.

MPCI Flurbiprofen 20%/Baclofen 10%/Dexamethasone 2% CR 210 #210gram: 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 04/06/14 and presents with pain in his mid back, lowers back, and left leg. The request is for MPCFI FLURBIPROFEN 20%/BACLOFEN 10%/DEXAMETHASONE 2% CR 210 #210 GRAM. There is no RFA provided and the patient is not currently working. MTUS Guidelines, Topical Analgesics Section, page 111 states: "Topical Analgesics: 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. Flurbiprofen, an NSAID, is indicated for peripheral joint arthritis/tendinitis. MTUS also states that many agents are compounded for pain control including antidepressants and that there is little to no research to support their use. Baclofen: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." The patient is diagnosed with low back pain. MTUS page 111 states that if one of the compounded topical products is not recommended, then the entire product is not. In this case, the requested topical compound contains Baclofen, which is not supported for topical use in lotion form, per MTUS. This request is not in accordance with guideline indications. Therefore, the request IS NOT medically necessary.