

Case Number:	CM15-0174623		
Date Assigned:	09/16/2015	Date of Injury:	02/02/2014
Decision Date:	10/23/2015	UR Denial Date:	08/27/2015
Priority:	Standard	Application Received:	09/04/2015

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 38-year-old male who sustained an industrial injury on February 2, 2014. Diagnoses have included left rotator cuff tear, left bicep tendon tear, chronic subscapularis tendinosis with tearing, and degenerative changes of the left AC joint. Documented treatment includes 6 chiropractic treatments in 2014; at least 6 sessions of physical therapy; an unspecified left shoulder injection with one week of pain relief; and, medication including oral analgesics which the progress note of July 31, 2015 states he was "not tolerating," and transdermal creams. The injured worker continues to complain of left shoulder pain and stiffness. Functional capacity evaluation of July 27, 2015 reveals difficulties with grasping and lifting; left-sided flexion 120 degrees versus right of 180, extension 35 versus 50, abduction 110 versus 180, adduction 30 versus 50, and external rotation 75 versus 90 on the right. Internal rotation was 80 on both sides. He is not working. The treating physician states July 31, 2015 that they are considering surgery. The plan of care also includes a request on August 17, 2015 for compound medications: Gabapentin 10 percent-Amitriptyline 5 percent-Capsaicin 0.025 percent; Cyclobenzaprine 10 percent-Lidocaine 2 percent; and, Flurbiprofen 20 percent-Lidocaine 5 percent which were denied August 27, 2015.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gabapentin 10%/Amitriptyline 5%/ Capsaicin 0.025% 150gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

Decision rationale: The patient was injured on 02/02/14 and presents with shoulder pain. The request is for Gabapentin 10%/Amitriptyline 5%/ Capsaicin 0.025% 150 gm. The RFA is dated 08/17/15 and the patient is to remain off of work until 08/21/15. 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". MTUS, page 29, Capsaicin, topical, Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain. Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. The patient is diagnosed with left rotator cuff tear, left bicep tendon tear, chronic subscapularis tendinosis with tearing, and degenerative changes of the left AC joint. 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.

Cyclobenzaprine 10%/ Lidocaine 2% 150gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

Decision rationale: The patient was injured on 02/02/14 and presents with shoulder pain. The request is for Cyclobenzaprine 10%/Lidocaine 2% 150 gm. The RFA is dated 08/17/15 and the

patient is to remain off of work until 08/21/15. 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.

Cyclobenzaprine is a muscle relaxant and is not supported for any topical formulation. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for 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. The patient is diagnosed with left rotator cuff tear, left bicep tendon tear, chronic subscapularis tendinosis with tearing, and degenerative changes of the left AC joint. MTUS page 111 states that if one of the compounded topical product is not recommended, then the entire product is not. In this case, the requested topical compound consists of Cyclobenzaprine and Lidocaine is not indicated for use as a topical formulation. Therefore, the requested compounded topical is not medically necessary.

Flurbiprofen 20%/ Lidocaine 5% 150gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

Decision rationale: The patient was injured on 02/02/14 and presents with shoulder pain. The request is for Flurbiprofen 20%/ Lidocaine 5% 150 gm. The RFA is dated 08/17/15 and the patient is to remain off of work until 08/21/15. 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. Flurbiprofen, an NSAID, is indicated for peripheral joint arthritis/tendinitis. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for 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. The patient is diagnosed with left rotator cuff tear, left bicep tendon tear, chronic subscapularis tendinosis with tearing, and degenerative changes of the left AC joint. MTUS Guidelines page 111 do not recommend a compounded product if one of the compounds are not indicated for use. In this case, Lidocaine (non-patch form) is not indicated for topical cream. The requested topical cream is not medically necessary.