

Case Number:	CM15-0127442		
Date Assigned:	07/14/2015	Date of Injury:	06/16/2012
Decision Date:	08/11/2015	UR Denial Date:	06/04/2015
Priority:	Standard	Application Received:	07/01/2015

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: North Carolina
 Certification(s)/Specialty: Family Practice

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 female who sustained an industrial injury on 04/18/12. Initial complaints and diagnoses are not available. Treatments to date include physical therapy and topical compounds. Diagnostic studies are not addressed. Current complaints include upper thoracic, bilateral cervical, right shoulder, left elbow, right arm, and right thoracic pain. Current diagnoses include fracture of radius epicondylitis of the elbow, adhesive capsulitis shoulder, shoulder tendinitis, and rotator cuff syndrome. In a progress note dated 05/28/15 the treating provider reports the plan of care as physical therapy, and medications including Lidoderm patches and a compound of FCL (Flurbiprofen/baclofen/dexamethasone/menthol/camphor/capsaicin/hyaluronic acid). The requested treatment includes a compound of Flurbiprofen/baclofen/dexamethasone/menthol/camphor/capsaicin/hyaluronic acid.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbiprofen 20%, Baclofen 2%, Dexamethasone 2%, Menthol 2%, Camphor 2% capsaicin 0.0375%, Hyaluronic acid 0.20% 180gms: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 111-113.

Decision rationale: The California chronic pain medical treatment guidelines section on topical analgesics states: Recommended as an option as indicated below. 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. (Namaka, 2004) 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. (Colombo, 2006) 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, biogenicamines, 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. The requested medication contains ingredients (hyaluronic acid) which are not indicated per the California MTUS for topical analgesic use. Therefore, the request is not medically necessary.

Lidoderm patches: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical lidocaine Page(s): 111.

Decision rationale: The California chronic pain medical treatment guidelines section on topical lidocaine states: Lidocaine Indication: Neuropathic pain Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI antidepressants or an AED such as gabapentin or Lyrica). 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. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. In February 2007, the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical lidocaine. Those at particular risk were individuals that applied large amounts of this substance over large areas, left the products on for long periods of time, or used the agent with occlusive dressings. Systemic exposure was highly variable among patients. Only FDA-approved products are currently recommended. (Argoff, 2006) (Dworkin, 2007) (Khaliq-Cochrane, 2007) (Knotkova, 2007) (Lexi-Comp, 2008) Non-neuropathic pain: Not recommended. There

is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. (Scudds, 1995) This medication is recommended for localized peripheral pain. The patient has no documented failure of all first line agents indicated for the treatment of neuropathic pain as outlined above. Therefore criteria as set forth by the California MTUS as outlined above have not been met and the request is not medically necessary.