

<b>Case Number:</b>	CM14-0155437		
<b>Date Assigned:</b>	09/25/2014	<b>Date of Injury:</b>	05/19/1997
<b>Decision Date:</b>	10/27/2014	<b>UR Denial Date:</b>	09/22/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/23/2014

### 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 Family 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 55-year-old male patient who reported an industrial injury to his back on 5/19/1997, over 17 years ago, attributed to the performance of his usual and customary job tasks. The patient is documented to have complaints of pain to the neck, upper back, low back and burning pain to the groin due to his prior abdominal surgery. The objective findings on examination included no acute distress; ambulates with cane; wearing a lumbar corset; clean incision; tenderness palpation over the thoracic and lumbar paraspinals; gait is Motley antalgic; sensation is intact in the bilateral upper and lower extremities; 5-/5 left deltoid and biceps strength with the rest of the strength 5/5 including the lower extremities. The patient is being treated for the diagnosis of status post anterior lumbar interbody fusion at L4-L5 on 2/1/1999; possible lumbar radiculopathy; chronic pain syndrome; and failed back surgery syndrome. The patient was prescribed Percocet 10/325 mg #150; Lonox 2.5 mg/0.025 mg tid; lighted term patches; ketoprofen 75 mg PRN; Flexeril 7.5 mg; Prilosec 20 mg 1QD PRN; ammonium lactate lotion 5% one bottle; Lidoderm patches 5%.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Cyclobenzaprine 7.5mg tablet #30:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47; 128, Chronic Pain Treatment Guidelines muscle relaxants for pain Page(s): 63-64. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter-medications for chronic pain; muscle relaxants; cyclobenzaprine

**Decision rationale:** The prescription for Flexeril (cyclobenzaprine) 7.5 mg #30 is recommended for the short-term treatment of muscle spasms and not for the long-term treatment of chronic pain. The patient has been prescribed muscle relaxers on a long-term basis contrary to the recommendations of the CA MTUS. The patient is prescribed muscle relaxers on a routine basis for chronic pain. The muscle relaxers are directed to the relief of muscle spasms. The chronic use of muscle relaxants is not recommended by the CA MTUS, the ACOEM Guidelines, or the Official Disability Guidelines for the treatment of chronic pain. The use of muscle relaxants are recommended to be prescribed only briefly in a short course of therapy. There is no medical necessity demonstrated for the use of muscle relaxants for more than the initial short-term treatment of muscle spasms. There is a demonstrated medical necessity for the prescription of muscle relaxers on a routine basis for chronic neck, back, and knee pain. The cyclobenzaprine was used as an adjunct treatment for muscle and there is demonstrated medical necessity for the Cyclobenzaprine for the cited industrial injury. The continued prescription of a muscle relaxant was not consistent with the evidence-based guidelines. There is no demonstrated medical necessity for the use of cyclobenzaprine as a sleep aid. The California MTUS states that cyclobenzaprine is recommended for a short course of therapy. Limited, mixed evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants. Evidence-based guidelines state that this medication is not recommended to be used for longer than 2 to 3 weeks. There is no demonstrated medical necessity for the prescription of cyclobenzaprine 7.5 mg #30 for the effects of the industrial injury.

**Omeprazole 20mg capsule #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines anti-inflammatory medication Page(s): 67-68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter-medications for chronic pain; NSAIDs

**Decision rationale:** The MTUS Chronic Pain Medical Treatment Guidelines section on anti-inflammatory medications and gastrointestinal symptoms states; "Determine if the patient is at risk for gastrointestinal events." The medical records provided for review do not provide additional details in regards to the above assessment needed for this request. No indication or rationale for gastrointestinal prophylaxis is documented in the records provided. There are no demonstrated or documented GI issues attributed to NSAIDs for this patient. The patient was prescribed Omeprazole routine for prophylaxis with Naproxen. The protection of the gastric lining from the chemical effects of NSAIDs is appropriately accomplished with the use of the proton pump inhibitors such as Omeprazole. The patient is documented to be taking NSAIDs - Naproxen; however, there is no identified GI issues attributed to the prescribed Naproxen. There

is no industrial indication for the use of Omeprazole due to "stomach issues" or stomach irritation. The proton pump inhibitors provide protection from medication side effects of dyspepsia or stomach discomfort brought on by NSAIDs. The use of Omeprazole is medically necessary if the patient were prescribed conventional NSAIDs and complained of GI issues associated with NSAIDs. Whereas, 50% of patient taking NSAIDs may complain of GI upset, it is not clear that the patient was prescribed Omeprazole automatically. The prescribed opioid analgesic, not an NSAID, was accompanied by a prescription for Omeprazole without documentation of complications. There were no documented GI effects of the NSAIDs to the stomach of the patient and the Omeprazole was dispensed or prescribed routinely. There is no demonstrated medical necessity for BID dosing. There is no demonstrated medical necessity for the prescription for omeprazole 20 mg #60. There is no documented functional improvement with the prescribed omeprazole.

**Naproxen 550mg capsule #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines anti-inflammatory medications Page(s): 67-68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter--medications for chronic pain and NSAIDs

**Decision rationale:** The use of Anaprox/Naproxen 550 mg is consistent with the currently accepted guidelines and the general practice of medicine for musculoskeletal strains and injuries; however, there is no evidence of functional improvement or benefit from this NSAID. There is no evidence that OTC NSAIDs would not be appropriate for similar use for this patient. The prescription of Naproxen is not supported with appropriate objective evidence as opposed to the NSAIDs available OTC. The prescription of Naproxen should be discontinued in favor of OTC NSAIDs. There is no provided evidence that the available OTC NSAIDs were ineffective for the treatment of inflammation. The prescription for naproxen 550 mg #60 is not demonstrated to be medically necessary.

**Ammonium Lactate lotion 5% #2 bottles:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.drugs.com/pro/ammonium-lactate.html>, Indications and Usage for Ammonium Lactate

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: general disciplinary guidelines for the practice of medicine

**Decision rationale:** Ammonium lactate lotion: Ammonium lactate is a combination of lactic acid and ammonium hydroxide. Ammonium lactate is a moisturizer. Ammonium lactate is used to treat dry, scaly, itchy skin. The patient was prescribed ammonium lactate lotion for the treatment of the skin adjacent to the surgical incision. There is no rationale supported with

objective evidence to support the medical necessity of the prescribed and dispensed ammonium lactate lotion as opposed to the available OTC moisturizing lotions and creams available for dry skin. There is no demonstrated medical necessity for the dispensed ammonium lactate lotion 5% two bottles.

**Lidoderm 5% #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm Patches, Opioids.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47-48, Chronic Pain Treatment Guidelines anti-inflammatory medications; topical analgesics Page(s): 67-68; 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter medications for chronic pain; topical analgesics

**Decision rationale:** The prescription of topical Lidoderm 5% patches #30 was not demonstrated to be medically necessary and no objective evidence to support the medical necessity of the prescribed topical lidocaine for the cited diagnoses. The CA MTUS does not recommend the use of Lidoderm patches for pain control as the patches or ointment are only FDA approved for the treatment of neuropathic pain attributed to post herpetic neuralgia. The patient is being treated with Lidoderm patches for chronic back and neck pain. There is no medical necessity for the use of the Lidoderm patches for the objective findings documented on examination. The request for authorization of the Lidoderm patches is not supported with objective evidence and is not recommended as a first line treatment for the treatment of chronic shoulder pain. There is no objective evidence that the Lidoderm patches are more effective than the many available alternatives for the treatment of chronic pain. There is no objective evidence to support the use of Lidoderm patches for the stated symptoms, as there are available alternatives. There is no objective evidence to support the use of topical lidocaine for the treatment of the documented diagnoses. The applicable evidence-based guidelines state that more research is required prior to endorsing the use of Lidoderm patches for the treatment of chronic pain. The prescription of Lidoderm patches is FDA approved only for post herpetic neuralgia and is not to be used as a first line treatment. The provider provides no rationale for the use of the dispensed/prescribed Lidoderm patches over the readily available medical alternatives. The prescription of the Lidoderm patches is inconsistent with evidence-based guidelines. There are no prescribed antidepressants or gabapentin to support the medical necessity of Lidoderm topical patches. Evidence-based guidelines necessitate documentation of localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED, such as, gabapentin or Lyrica) to support the medical necessity of Lidoderm patch. The patient is not taking Neurontin, thus Lidoderm is not appropriate for the treatment of this patient. There is no objective evidence to support the use of Lidoderm patches for the continuous and daily treatment of chronic back pain. There is no current clinical documentation that indicates that the patient has a localized area of neuropathic pain for which this medication would be medically necessary. There is no demonstrated medical necessity for Lidoderm patches or topical lidocaine ointment to treat the effects of the industrial injury. ODG identifies that Lidoderm is the brand name for a lidocaine patch produced by [REDACTED]. Topical lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED, such as, gabapentin or Lyrica). This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. 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. Additionally, ODG states that topical

lidocaine 5% patch/ointment has been approved by the FDA for post-herpetic neuralgia, and is used off-label for diabetic neuropathy and other neuropathic pain. It has been shown to be useful in treating various chronic neuropathic pain conditions in open-label trials. (Argoff, 2006) (ODG, Pain Chapter). There is no demonstrated medical necessity for the prescribed Lidoderm 5% patches #30.