

<b>Case Number:</b>	CM14-0169426		
<b>Date Assigned:</b>	10/17/2014	<b>Date of Injury:</b>	05/27/2012
<b>Decision Date:</b>	12/05/2014	<b>UR Denial Date:</b>	09/29/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/14/2014

### 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 who reported an industrial injury on 5/27/2012, 2 years ago, attributed to the performance of his usual and customary job tasks. The patient complained of cervical spine pain; left elbow pain; thoracic spine pain; and lumbar spine pain. The pain was reported to be constant and radiated to the bilateral lower extremities left greater than right. The objective findings on physical examination were positive straight leg raise and tenderness to palpation on affected area as well as decreased range of motion. The left elbow range of motion was 0-110 with left lateral epicondylitis. The treating diagnoses included cervical spine sprain/strain, thoracic spine's brain/strain, and lumbar spine sprain/strain with left elbow sprain and strain. The treatment plan for the patient included a functional capacity evaluation; consultations medications; acupuncture and urine drug screen. The patient was placed on modified work with documented restrictions. The patient was prescribed Menthoderm 360 g gel; lens a patch (lidocaine 4%-menthol 1%) cyclobenzaprine 7.5 mg #90 and naproxen 550 mg #60.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Lenza Patch (Lidocaine 4% Menthol 1%) for night-time #30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47-48, Chronic Pain Treatment Guidelines Anti-Inflammatory Medications, Chronic Pain Chapter's, Topical Analgesics Page(s): 67-68, 111-1. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter Medications for Chronic Pain; Topical Analgesics.

**Decision rationale:** The CA MTUS does not recommend the use of Lenzapatch 4%-1% patches #30 for pain control as the patches are only FDA approved for the treatment of neuropathic pain attributed to post herpetic neuralgia. The patient is being treated with Lenzapatch 4%-1% patches #30 for chronic back/neck pain. There is no medical necessity for the use of the Lenzapatch 4%-1% patches #30 for the objective findings documented on examination. There is no objective evidence that the Lenzapatch 4%-1% patches #30 are more effective than the many available alternatives for the treatment of chronic pain. There is no objective evidence to support the use of Lenzapatch 4%-1% patches #30 for the stated symptoms as there are available alternatives. There is no objective evidence to support the use of topical Lenzapatch 4%-1% patches #30 for the treatment of the documented diagnoses. The applicable evidence-based guidelines state that more research is required prior to endorsing the use of Lenzapatch 4%-1% patches #30 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 Lenzapatch 4%-1% patches #30 over the readily available medical alternatives. The prescription of the Lenzapatch 4%-1% patches #30 is inconsistent with evidence-based guidelines. There are no prescribed antidepressants or gabapentin to support the medical necessity of Lenzapatch 4%-1% patches #30. 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. 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 Lenzapatch 4%-1% patches #30 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). Therefore, based on guidelines and a review of the evidence, the request for Lenzapatch 4%-1% patches #30 is not medically necessary.

**Cyclobenzaprine 7.5mg, 1/2-1 tab every 8-12 hrs prn #90: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain) Page(s): 64.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, 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, ACOEM Guidelines Chronic Pain Chapter, 2008, Muscle Relaxant, page 128.

**Decision rationale:** 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 no demonstrated medical necessity for the prescription of muscle relaxers on a routine basis for chronic back pain. The cyclobenzaprine was used as an adjunct treatment for muscle and there is no demonstrated medical necessity for the Cyclobenzaprine/Flexeril for the cited industrial injury. The continued prescription of a muscle relaxant was not consistent with the evidence-based guidelines. 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 for the effects of the industrial injury. There is no demonstrated medical necessity for the prescription of Therefore, based on guidelines and a review of the evidence, the request for Cyclobenzaprine 7.5 mg #90 is not medically necessary.

**Naproxen 550mg, 1 tab 2 x a day #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Naproxen Page(s): 73.

**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 #60 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 rationale to support the medical necessity of #60 tabs. 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. Therefore, based on guidelines and a review of the evidence, the request for Naproxen 550 mg #60 is not medically necessary.

**Menthoderm (Methyl Salicylate 15% Menthol 10%) 360gm gel, apply 3 x a day: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate topicals Page(s): 105.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Topical Analgesics, Topical Analgesic Compounded; ACOEM Guidelines Chronic Pain Chapter, 2008, Pain Chapter, page 128.

**Decision rationale:** There is no Orthopedic clinical documentation submitted with the billing to demonstrate the use of the topical creams for appropriate diagnoses or for the recommended limited periods of time. It is not clear that the topical medications are medically necessary in addition to prescribed oral medications. There is no provided subjective/objective evidence that the patient has failed or not responded to other conventional and recommended forms of treatment for relief of the effects of the industrial injury. Only if the subjective/objective findings are consistent with the recommendations of the ODG, then topical use of topical preparations is only recommended for short-term use for specific orthopedic diagnoses. The use of topical NSAIDs is documented to have efficacy for only 2-4 weeks subsequent to injury, and thereafter, is not demonstrated to be as effective as oral NSAIDs. There is less ability to control serum levels and dosing with the topicals. The patient is not demonstrated to have any GI issue at all with NSAIDs. The use of the topical creams/gels does not provide the appropriate therapeutic serum levels of medications due to the inaccurate dosing performed by rubbing variable amounts of creams on areas that are not precise. The volume applied and the times per day that the creams are applied are variable and do not provide consistent serum levels consistent with effective treatment. There is no medical necessity for the addition of creams to the oral medications in the same drug classes. There is no demonstrated evidence that the topicals are more effective than generic oral medications. The prescription is accompanied with a state of medical necessity by the vendor which states that "compounded medications are not absorbed by the stomach so they do not cause any of the dangerous side effects that may be experienced by taking medications orally (ie damage to the liver and kidneys). In fact, medications that are transdermal or oral enter the blood stream and are ultimately broken down in the liver or kidneys. The breakdown of the prescribed topical medication still occurs in the kidneys and liver." "Compounded medications are absorbed through the skin so less medication enters the blood stream. The benefit of this is that there is reduced chance of building tolerance to drugs thereby curbing any potential addiction to medication." There is no objective evidence to support this contention and high serum levels can be achieved through transdermal applications. The serum levels can be similar and have the same propensity towards tolerance. "Compounds have fewer possibilities of drug interactions because less of the medication enters the blood stream," is not supported with objective evidence. The ability to interact with other medications in the blood stream is the same whether the route of absorption is oral or transdermal. "Compounds provide faster relief than

medications taken orally. With compound medications you get fast pain relief to the affected area within a matter of minutes of application," is also not supported with objective evidence. The use of Methoderm topical gel 360 g. not supported by the applicable ODG guidelines as cited below. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or demonstrated to be appropriate. There is no documented objective evidence that the patient requires both the oral medications and the topical compounded medication for the treatment of the industrial injury. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or appropriate - noting the specific comment, "There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder." The objective findings in the clinical documentation provided do not support the continued prescription of for the treatment of chronic low back pain. Therefore, based on guidelines and a review of the evidence, the request for Methoderm is not medically necessary.