

Case Number:	CM14-0023804		
Date Assigned:	06/11/2014	Date of Injury:	08/01/2006
Decision Date:	09/25/2014	UR Denial Date:	02/17/2014
Priority:	Standard	Application Received:	02/25/2014

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 female patient who reported an industrial injury to the back, UE, and shoulder on 8/1/2006, over eight (8) years ago, attributed to the performance of her job tasks. The patient was documented to complain of bilateral shoulder, arm, low back, and leg pain with numbness and tingling and decreased grip strength. The objective findings on examination included positive Tinel's sign at the elbow suggesting cubital tunnel syndrome; Tinel's sign at the wrist for carpal tunnel syndrome. The patient had a prior electrodiagnostic study which was positive for carpal tunnel syndrome of the right wrist and cubital tunnel syndrome with ulnar neuropathy of the right elbow. The diagnoses included rotator cuff rupture; ulnar nerve lesion; carpal tunnel syndrome; cervical spine degenerative disc disease; lumbar spine degenerative disc disease; medial epicondylitis; and thoracic spine degenerative disc disease. The patient was noted to be status post left elbow medial epicondylectomy with ulnar nerve transposition; status post open rotator cuff repair times two left shoulder; status post open and subsequent arthroscopic rotator cuff repair of the right shoulder times three; status post laminectomy/discectomy at L1 and possible L2 levels. The patient was reported to have symptoms consistent with intermittent insomnia, sleep disorder; daytime impairment. The patient was prescribed Flexeril 7.5 mg #90; Lunesta 2 mg #30; Lidoderm patches unspecified; and LidoKeto topical compounded ointment unspecified.

IMR ISSUES, DECISIONS AND RATIONALES

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

FLEXERIL 7.5 MG, #90: Upheld

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

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.

Decision rationale: The prescription for Flexeril (Cyclobenzaprine) 7.5 mg #90 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 MTUS Chronic Pain Guidelines. 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 MTUS Chronic Pain Guidelines, 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 back, UE, and neck 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. The MTUS Chronic Pain Guidelines 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 #90 for the effects of the industrial injury.

LUNESTA 2 MG, #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Pain Chapter.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter insomnia.

Decision rationale: The prescription for Lunesta is recommended only for the short-term treatment of insomnia for two to six weeks by the ODG. The patient is being prescribed Lunesta on a routine basis. There is no provided subjective/objective evidence to support the prescription for the use of Lunesta on an industrial basis for this patient for the ongoing prolonged period of time. The patient has exceeded the recommended time period for the use of this short-term sleep aide. There is no medical necessity for the prescription of Lunesta on a nightly basis. There is no

rationale to support the #30 per month Lunesta for the insomnia associated with chronic pain. The patient has been prescribed a sedative hypnotic for a prolonged period time and has exceeded the time period recommended by evidence-based guidelines. The continued use of Lunesta on a nightly basis is inconsistent with evidence-based medicine and is not effective for the patient leading to dependency issues. There is no recommendation for Lunesta for any sleep disturbance issue or for insomnia. The patient has been prescribed Lunesta for a period of time without any documentation of a failure of the multiple available over-the-counter sleep aids. The patient should be discontinued from the recently prescribed Lunesta in favor of other available remedies that may be obtained over the counter. There needs to be further documentation in the medical record that the insomnia is persistent or related to the industrial injury. The patient is prescribed a sedative hypnotic on a nightly basis and not PRN insomnia. The request for Lunesta 3 mg #90 suggests the patient is taking a sleeping medication every night for the next 3 months. There is no demonstrated medical necessity for the use of Lunesta when only short-term treatment is recommended by evidence guidelines. The use of nightly sleeping aids is not medically necessary. The sedative hypnotic is known to lead to issues of dependency and abuse. There is no demonstrated medical necessity for the continuation of Lunesta 2 mg #30.

LIDODERM PATCHES: Upheld

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

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; 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter medications for chronic pain; topical analgesics.

Decision rationale: The MTUS Chronic Pain Guidelines 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 shoulder, neck, back, or UE 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 neck 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 neck or 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. The ODG identifies that Lidoderm is the brand name for a lidocaine patch produced by Endo Pharmaceuticals. 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. Additionally, the 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 patches 1% #60 as dispensed to the patient on 4/25/2014.

LIDOKETO-OINTMENT: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, Chronic Pain Treatment Guidelines TOPICAL ANALGESICS; ANTI-INFLAMMATORY MEDICATIONS Page(s): 112-113; 22, 67-68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--topical analgesics; topical analgesics compounded.

Decision rationale: There is no clinical documentation submitted to demonstrate the use of the topical gels for appropriate diagnoses or for the recommended limited periods of time. It is not clear that the topical compounded 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. There is no provided rationale supported with objective evidence to support the prescription of the topical compounded cream. There is no documented efficacy of the prescribed topical compounded analgesics with no assessment of functional improvement. The patient is stated to have reduced pain with the topical creams however there is no functional assessment and no quantitative decrease in pain documented. 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. There is no demonstrated medical necessity for topical NSAIDs for chronic pain for a prolonged period of time. The request for the topical NSAID compounded topical ointment LidoKeto unspecified is not medically necessary for the treatment of the patient for the diagnosis of the chronic pain to the lower back. The use of the topical gels/creams does not provide the appropriate therapeutic serum levels of medications due to the inaccurate dosing performed by rubbing variable amounts of gels on areas that are not precise. The volume applied and the times per day that the gels are applied are variable and do not provide consistent serum levels consistent with effective treatment. There is no medical necessity for the addition of gels 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 use of compounded topical ointment LidoKeto unspecified not supported by the applicable evidence-based guidelines as cited above. 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 analgesic medication for the treatment of the industrial injury.