MAXIMUS Federal Services

Case Number:	CM14-0171213		
Date Assigned:	10/23/2014	Date of Injury:	01/11/2006
Decision Date:	11/25/2014	UR Denial Date:	10/01/2014
Priority:	Standard	Application Received:	10/16/2014

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 56-year-old female patient who reported an industrial injury to the lower back on 1/11/2006, almost nine (9) years ago, attributed to the performance of her usual and customary job tasks. The treating physician requested Lenzapatch 4%-1% #10 in addition to the prescribed Sentra a.m. #60; Sentra PM #60; and Theramine #60. There was no documentation of the subjective complaints from the patient or objective findings by examination. Request for additional information to support medical necessity were not answered. The requested patches contained lidocaine HCl 4% and menthol 1% along with aloe vera leaf, Arnica Montana; Indian Frankincense; green tea leaf and ethylhexylglycerine.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lenzapatch 4% 1% PS, QTY: 10: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Boswellia Serrata Resin (Frankincense) [DWC] and Topical Analgesic. Decision based on Non-MTUS Citation DailyMed http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=dc50bObf-5929-4497-85e8-Icb5aed67ad7: Lenzapatch

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 Lenzapatch 4%-1% patches #10 is not demonstrated to be medically necessary and no objective evidence to support the medical necessity of the prescribed topical lidocaine for the cited diagnoses. There is no demonstrated medical necessity for the dietary supplements incorporated into the Lidoderm/menthol topical patches. The CA MTUS does not recommend the use of Lenzapatch 4%-1% patches #10 for pain control as the patches or ointment is only FDA approved for the treatment of neuropathic pain attributed to post herpetic neuralgia. The patient is being treated with Lenzapatch 4%-1% patches #10 for chronic back pain. There is no medical necessity for the use of the Lenzapatch 4%-1% patches #10 for the objective findings documented on examination.The request for authorization of the Lenzapatch 4%-1% patches #10 is not supported with objective evidence and is not recommended as a first line treatment for the treatment of chronic back pain. There is no objective evidence that the Lenzapatch 4%-1% patches #10 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 #10 for the stated symptoms as there are available alternatives. There is no objective evidence to support the use of topical Lenzapatch 4%-1% patches #10 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 #10 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 #10 over the readily available medical alternatives. The prescription of the Lenzapatch 4%-1% patches #10 is inconsistent with evidence-based guidelines. There are no prescribed antidepressants or gabapentin to support the medical necessity of Lenzapatch 4%-1% patches #10.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 #10 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 Lenzapatch 4%-1% patches #10.