

Case Number:	CM14-0079624		
Date Assigned:	09/24/2014	Date of Injury:	10/03/2012
Decision Date:	10/24/2014	UR Denial Date:	05/29/2014
Priority:	Standard	Application Received:	05/30/2014

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 32-year-old female who reported an industrial injury on 10/3/2012, over two (2) years ago, attributed to the performance of her usual and customary job tasks. The patient was evaluated by an AME and reported ongoing neck, back, right shoulder, right upper extremity, and right lower extremity pain. The patient reported depression and anxiety. It was noted that diagnostic studies were essentially normal. The AME diagnose the patient with lumbar strain; lumbar degenerative disc disease; L4-L5 stenosis; normal electrodiagnostic studies with no evidence of lumbar radiculopathy; cervical strain; cervical spondylosis; normal cervical MRI with no evidence of cervical radiculopathy; myofascial pain syndrome; no evidence of thoracic injuries; and chronic pain syndrome was subjective complaints exceeding objective findings and significant functional overlay. The patient complains of chronic pain. The patient was being treated for the diagnoses of cervical brachial syndrome, backache, arm pain, Enthesopathy of the hip. The patient's medication regimen had not changed. The patient was prescribed Lidoderm 5% patches #30 refill x3; Neurontin hundred milligrams #90 with refill x3; Norflex 100 mg #60 with refill x3; Unisom sleep aid 25 mg #30 refill x3; Zipsor (diclofenac) 25 mg #120 with refill x3; and Prilosec 20 mg #60 with refill x3.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lidoderm 5% patch #30, 3 refills: Upheld

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

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 pain chapter medications for chronic pain; topical analgesics Non-Mtus Pain Chapter Medications For Chronic Pain; Topical Analgesics and Also Official Disability Guidelines (ODG).

Decision rationale: The prescription of topical Lidoderm 5% patches #30 with refill x3 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 pain and the AME has documented no neuropathic 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 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. Official Disability Guidelines (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. 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 with refills x3.

Neurotin 100mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines anti-epilepsy drugs specific anti-epilepsy drugs gabapentin Page(s): 16 18. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) chronic pain chapter 8/8/2008 page 110

Decision rationale: The treating physician has prescribed Neurontin/gabapentin 100 mg #90 with refills x3 to the patient for the treatment of neuropathic pain over a prolonged period of time with the documentation of efficacy noted in the ongoing clinical record. The treating physician has not noted decreased pain with the use of gabapentin. There is no documentation of functional improvement with the prescription of the gabapentin 100 mg tid. The AME diagnoses do not include any neuropathic pain components. The patient is not noted to have evidence of neuropathic pain. The patient is not demonstrated to have neuropathic pain for which Gabapentin has provided functional improvement. The prescription of Gabapentin (Neurontin) was not demonstrated to have been effective for the patient for the chronic pain issues. The treating physician has provided this medication for the daily management of this patient's chronic pain. The prescription of Gabapentin (Neurontin) is recommended for neuropathic pain; however, the ACOEM Guidelines. Gabapentin or pregabalin is not recommended for treatment of chronic, non-neuropathic pain by the ACOEM Guidelines. The ACOEM Guidelines revised chronic pain chapter states that there is insufficient evidence for the use of Gabapentin/Neurontin for the treatment of axial lower back pain; chronic lower back pain; or chronic lower back pain without radiculopathy. The CA MTUS and the Official Disability Guidelines state that there is insufficient evidence to support the use of Gabapentin or Lyrica for the treatment of chronic axial lower back pain. The prescription of Gabapentin for neuropathic pain was supported with objective findings on physical examination. There was objective evidence that the recommended conservative treatment with the recommended medications have been provided. The use of Gabapentin/Lyrica should be for neuropathic pain. Presently, there is documented objective evidence of neuropathic pain for which the use of Gabapentin is recommended. The patient has demonstrated neuropathic pain secondary to a nerve impingement neuropathy as neuropathic pain for which Gabapentin/Lyrica is recommended. The prescription of Gabapentin is recommended for neuropathic pain and is used to treat postherpetic neuralgia and painful polyneuropathy such as diabetic polyneuropathy. Anti-epilepsy drugs (AEDs) are recommended on a trial basis (Lyrica/gabapentin/pregabalin) as a first-line therapy for painful polyneuropathy such as diabetic polyneuropathy. The updated chapter of the ACOEM Guidelines does not recommend the use of Lyrica or Gabapentin (Neurontin) for the treatment of axial back pain or back pain without radiculopathy. The use of Gabapentin is for neuropathic pain; however, evidence-based guidelines do not recommend the prescription of Gabapentin for chronic lower back pain with a subjective or objective radiculopathy and favors alternative treatment. The request for gabapentin 300 mg #60 x2 refills is demonstrated to be medically necessary; there is no demonstrated medical necessity for gabapentin 100 mg #90 with refills x3. There was no rationale supported with objective evidence provided by the treating physician to support the medical necessity of Neurontin when the AME has diagnosed the patient with no neuropathic pain. The request for Neurontin is not medically necessary.

Norflex 100mg #60, 3 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxant Page(s): 63.

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 pain chapter-medications for chronic pain; muscle relaxants; cyclobenzaprine

Decision rationale: The prescription for Norflex (Orphenadrine ER) 100 mg #60 is not demonstrated to be medically necessary in the treatment of the cited diagnoses. The chronic use of muscle relaxants is not recommended by the ACOEM Guidelines or the Official Disability Guidelines for the treatment of chronic low back pain. The use of muscle relaxants are recommended to be prescribed only briefly for a short course of treatment for muscle spasms and there is no recommendation for chronic use. The patient was not documented to have muscle spasms to the back. The prescription for orphenadrine/Norflex is not demonstrated to be medically necessary for the effects of the industrial injury 2 years ago. The California MTUS states that non-sedating muscle relaxants are to be used with caution as a second line option for short-term treatment of acute exacerbations in patients with chronic low back pain. Muscle relaxants may be effective in reducing pain and muscle tension and increasing mobility. However, in most low back pain cases there is no benefit beyond NSAIDs in pain and overall improvement. There is no additional benefit shown in combination with NSAIDs. Efficacy appears to be diminished over time and prolonged use of some medications in this class may lead dependence. There is no current clinical documentation regarding this medication. A prescription for a muscle relaxant no longer appears to be medically reasonable or medically necessary for this patient. Additionally muscle relaxants are not recommended for long-term use. There was no documented functional improvement through the use of the prescribed Norflex/Orphenadrine ER 100 mg #60 with refill x3. The request for Norflex is not medically necessary.

Unisom Cleep Aid 25mg #30, 3 refills: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain Chapter--insomnia and Zolpidem Disciplinary Guidelines for the general practice of medicine Also Non-MTUS Official Disability Guidelines (ODG)

Decision rationale: Unisom 25 mg #30 with refill x3 is recommended only for the short-term treatment of insomnia for two to six weeks. The Unisom 25 mg has been prescribed to the patient for a prolonged period of time. The use of Unisom or any other sleeper has exceeded the ODG guidelines. The prescribing physician does not provide any rationale to support the medical necessity of Unisom for insomnia or documented any treatment of insomnia to date. The patient is being prescribed the Unisom for insomnia due to chronic pain simply due to the rationale of chronic pain without demonstrated failure of OTC remedies. There is no provided subjective/objective evidence to support the use of Unisom 5 mg over the available OTC remedies. The patient has exceeded the recommended time period for the use of this short-term sleep aide. There is no demonstrated functional improvement with the prescribed Unisom. There

is no documentation of alternatives other than Unisom have provided for insomnia or that the patient actually requires sleeping pills. The patient is not documented with objective evidence to have insomnia or a sleep disorder at this point in time or that conservative treatment is not appropriate for treatment. There is no evidence that sleep hygiene, diet and exercise have failed for the treatment of sleep issues. There is no demonstrated failure of the multiple sleep aids available OTC. The CA MTUS and the ACOEM Guidelines are silent on the use of sleeping medications. The ODG does not recommend the use of benzodiazepines in the treatment of chronic pain. Unisom is not a true benzodiazepine; however, retains some of the same side effects and is only recommended for occasional use and not for continuous nightly use. There is no medical necessity for the prescribed Unisom 25 mg with refill x3.

Prilosec 20mg #60, 3 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines anti-inflammatory medications Page(s): 67-68. Decision based on Non-MTUS Citation 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 diclofenac. 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 diclofenac; however, there was no documented GI risks. 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 Prilosec 20 mg #60 with refill x3.