

Case Number:	CM15-0048683		
Date Assigned:	03/20/2015	Date of Injury:	07/16/2008
Decision Date:	05/15/2015	UR Denial Date:	03/02/2015
Priority:	Standard	Application Received:	03/16/2015

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: Arizona, Michigan

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 50 year old male, who sustained an industrial injury on 07/16/2008. The injured worker was diagnosed as having lumbar radiculopathy, status post laminectomy and instrumentation L5-S1, chronic pain syndrome, chronic pain related to insomnia, myofascial syndrome, neuropathic pain, severe chronic pain related depression and prescription narcotic dependence. According to a progress report dated 02/11/2015, the injured worker complained of low back pain radiating down the left leg, depression and anxiety. The provider noted that the injured worker was having difficulty sleeping and that Trazodone and Benadryl was no longer working. Treatment plan included discontinuation of Trazodone, Benadryl and Gabadone. Medication regimen was to include Clonidine, Lorazepam, Norco, Prilosec, Gabapentin, Fluriflex, Sentra, Terocin patches and Lunesta.

IMR ISSUES, DECISIONS AND RATIONALES

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

Clonidine 0.2mg #90: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation PDR, National Library of Medicine.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Clonidine, Intrathecal Page(s): 34-35.

Decision rationale: Per the MTUS, Clonidine (Catapres) is a direct-acting adrenergic agonist prescribed historically as an antihypertensive agent, but it has found new uses, including treatment of some types of neuropathic pain. However it is not clear from a review of the injured workers medical records the indication for the use of clonidine and without this information it is not medical necessary.

Norco 10/325mg #240: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 81. Decision based on Non-MTUS Citation ODG, Pain Chapter.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96 (78 89, 95).

Decision rationale: Per the MTUS, opioids should be discontinued if there is no overall improvement in function, unless there are extenuating circumstances, Opioids should be continued if the patient has returned to work or has improved functioning and pain. On going management actions should include prescriptions from a single practitioner, taken as directed and all prescriptions from a single pharmacy. The lowest possible dose should be prescribed to improve pain and function. Documentation should follow the 4 A's of analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors. Long term users of opioids should be regularly reassessed. In the maintenance phase the dose should not be lowered if it is working. Also, patients who receive opioid therapy may sometimes develop unexpected changes in their response to opioids, which includes development of abnormal pain, change in pain pattern, persistence of pain at higher levels than expected. when this happens opioids can actually increase rather than decrease sensitivity to noxious stimuli. it is important to note that a decrease in opioid efficacy should not always be treated by increasing the dose or adding other opioids, but may actually require weaning. Unfortunately a review of the injured workers medical records do not reveal documentation of the injured workers pain and functional status improvement with the use of opioids as required by the MTUS for ongoing management and without this information, it is not medical necessary.

Lorazepam 1mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

Decision rationale: The MTUS does not recommend long term use of benzodiazepines, long term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Tolerance to all of its effects develop within weeks to months, and long term use may

actually increase anxiety, a more appropriate treatment for anxiety disorder is an antidepressant. Chronic benzodiazepines are the treatment of choice in very few conditions. A review of the injured workers medical records do not reveal extenuating circumstances that would warrant deviating from the guidelines and clear indications for the use of this medication is not found in the medical records that are available to me and without this information, the request is not medically necessary.

Prilosec 20mg #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: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) NSAIDs, GI symptoms and cardiovascular risk.

Decision rationale: Per the MTUS, Clinicians should weigh the indications for NSAIDs against both GI and cardiovascular risk factors according to specific criteria listed in the MTUS and a selection should be made based on these criteria 1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Per the ODG, PPI's are Recommended for patients at risk for gastrointestinal events. Prilosec (omeprazole), Prevacid (lansoprazole) and Nexium (esomeprazole magnesium) are PPIs. Healing doses of PPIs are more effective than all other therapies, although there is an increase in overall adverse effects compared to placebo. Nexium and Prilosec are very similar molecules. (Donnellan, 2010) In this RCT omeprazole provided a statistically significantly greater acid control than lansoprazole. (Miner, 2010) In general, the use of a PPI should be limited to the recognized indications and used at the lowest dose for the shortest possible amount of time. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Studies suggest, however, that nearly half of all PPI prescriptions are used for unapproved indications or no indications at all. Many prescribers believe that this class of drugs is innocuous, but much information is available to demonstrate otherwise. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of omeprazole or lansoprazole had been recommended before prescription Nexium therapy (before it went OTC). The other PPIs, Protonix, Dexilant, and Aciphex, should be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011). A review of the injured workers medical records that are available to me do not reveal any subjective, objective or historical findings of gastrointestinal problems, nor is it mentioned that he is currently on NSAID's, without this information the request is not medically necessary.

Fluriflex ointment: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 11-113.

Decision rationale: Per the MTUS, topical analgesics are recommended as an option, they are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. Fluriflex ointment is a compounded product of flurbiprofen and cyclobenzaprine. Per the MTUS, there is no evidence to support the use of any muscle relaxant as a topical agent, therefore based on the guidelines the request for fluriflex ointment is not medically necessary.

Terocin patches #30: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 11-113.

Decision rationale: Per the MTUS, topical analgesics are recommended as an option, they are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. Lidocaine in the form of a dermal patch, has been designated for orphan status by the FDA for neuropathic pain, A review of the injured workers medical records that are available to me reveal documentation of neuropathic pain and the request for Terocin patches # 30 is medically necessary.

Lunesta 2mg #30: Overturned

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental illness and stress/ insomnia, insomnia treatment.

Decision rationale: MTUS did not specifically address the use of Lunesta, therefore other guidelines were consulted. Per the ODG, "Eszopicolone (Lunesta) has demonstrated reduced sleep latency and sleep maintenance. The only benzodiazepine-receptor agonist FDA approved

for use longer than 35 days. The ODG recommends correcting deficits, as nonrestorative sleep is one of the strongest predictors for pain and that treatment be based on the etiology. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. Primary insomnia is generally addressed pharmacologically. Secondary insomnia may be treated with pharmacological and/or psychological measures. The specific component of insomnia should be addressed: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; & (d) Next-day functioning. A review of the injured workers medical records reveal chronic pain with co-morbid psychiatric illness and insomnia and the use of Lunesta is medically necessary and appropriate in this injured worker.

Sentra PM #60: Upheld

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

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

Decision rationale: The MTUS did not specifically address the use of Sentra PM in the injured worker and therefore other guidelines were consulted. Per the ODG, it is not recommended. Sentra PM is a medical food intended for use in management of sleep disorders associated with depression. It is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan, hawthorn berry, cocoa, ginkgo biloba, and acetyl L-carnitine. Based on this guideline the request for Sentra PM # 60 is not medically necessary.