MAXIMUS Federal Services

Case Number:	CM15-0036398		
Date Assigned:	03/04/2015	Date of Injury:	03/23/2012
Decision Date:	04/23/2015	UR Denial Date:	02/04/2015
Priority:	Standard	Application Received:	02/26/2015

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:

This 53-year-old man sustained an industrial injury on 3/23/2012. The mechanism of injury is not detailed. Current diagnoses include lumbar degenerative disc disease, myofascial pain, sleep issues, and poor coping. Treatment has included oral medications and use of a TENS unit. Physician notes on a PR-2 dated 1/2/2015 show complaints of low back pain. The worker states his current medication regimen has been very helpful. Recommendations include home exercise program, continuing current medication regimen, continue TENS, pending psychiatrist evaluation and psychologist evaluation, await functional capacity evaluation, and monthly pain management follow up. On 2/4/2015, Utilization Review evaluated prescriptions for Diclofenac, Omeprazole, LidoPro Cream, Lunesta, Cyclobenzaprine, and TENS patches, that were submitted on 2/29/2015. The UR physician noted the following: regarding the LidoPro, there is no documentation of failed first line medication trials. Further, the non-dermal patch formulation is not recommended. Regarding Lunesta, there is no documentation of the worker's sleep history. Regarding Cyclobenzaprine, this medication is not recommended to be used long term. Further, there is no documentation of spasms, cramping, or trigger points. Regarding TENs patches, there is no clear objective evidence of functional improvement. Regarding Diclofenac, there is no documentation of objective functional improvement. Regarding Omeprazole, there is no documentation of gastrointestinal events. The MTUS, ACOEM Guidelines, (or ODG) was cited. The requests were denied and subsequently appealed to Independent Medical Review.

IMR ISSUES, DECISIONS AND RATIONALES

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

LidoPro cream 121gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

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. A review of the injured workers medical records that are available to me does not show a trial of recommended first line agents that have failed, therefore the request for LidoPro cream 121gm is not medically necessary.

Lunesta 2mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Med Lett Drugs Ther 2005 Feb 28;47 (1203): 17-9 Eszopiclone (Lunesta), a new hypnotic.

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/ Eszopicolone (Lunesta).

Decision rationale: The MTUS / ACOEM did not specifically address the use of Lunesta therefore other guidelines were consulted. Per the ODG, Eszopicolone (Lunesta) is not recommended for long-term use, but recommended for short-term use. Recommend limiting use of hypnotics to three weeks maximum in the first two months of injury only, and discourage use in the chronic phase. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. In this study, eszopicolone (Lunesta) had a Hazard ratio for death of 30.62 (C.I., 12.90 to 72.72), compared to zolpidem at 4.82 (4.06 to 5.74). In general, receiving hypnotic prescriptions was associated with greater than a threefold increased hazard of death even when prescribed less than 18 pills/year. (Kripke, 2012) The FDA has lowered the recommended starting dose of eszopiclone (Lunesta) from 2 mg to 1 mg for both men and women. Previously recommended doses can cause impairment to driving skills, memory, and coordination as long as 11 hours after the drug is taken. Despite these long-lasting effects, patients were often unaware they were impaired. (FDA, 2014). This medication caries serious risk and while it is noted that the injured worker was sleeping better with 1 mg there is no clear documentation as to why the

medication was increased to 2 mg, Lunesta is not recommended for long term use, and a review of the injured workers medical records indicate long term use of Lunesta with no reported measurable improvement in duration or quality of sleep, without this information, is not medically necessary.

Cyclobenzaprine 7.5mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril) Page(s): 41-42. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) / Cyclobenzaprine (Flexeril).

Decision rationale: Regarding the request for cyclobenzaprine, the MTUS recommends a short course of this medication as an option in the management of chronic pain. The effect of cyclobenzaprine is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. This medication is not recommended to be used for longer than 2-3 weeks. The patient does not appear to be a candidate for continued use of cyclobenzaprine. Records reflect the patient has been prescribed cyclobenzaprine on a long-term basis, and guidelines do not recommend use for over 2-3 weeks. Continued use of cyclobenzaprine would not fall within guideline recommendations and would put the patient at increased risk for adverse effects. Therefore, the request for cyclobenzaprine 7.5mg # 60 is not medically necessary.

Tens patch x 4: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TENS (transcutaneous electrical nerve stimulation.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Transcutaneous Electrotherapy Page(s): 114-121.

Decision rationale: Per the MTUS, transcutaneous electrical nerve stimulation (TENS) is not recommended as a primary treatment modality. However, it may be tried under specific criteria as documented in the MTUS, which include documentation of pain of at least 3 months duration and there is evidence that other appropriate pain modalities including medication have been tried and failed. A one month trial period should include documentation of how often unit was used, as well as outcomes in terms of pain relief and function and other ongoing pain treatment, a treatment plan including specific short and long term goals of treatment with the unit should be submitted and a 2 lead unit is generally recommended, if a 4 lead unit is recommended, there must be documentation of why this is necessary. A review of the injured workers medical records that are available to me reveals that the injured worker did not appear to have had a satisfactory response to the one trial documented in his medical records in which his pain level went from 8/10 to 7/10, his records also did not include documentation of the criteria for use as recommended in the MTUS and there is no documentation for why a 4 lead unit is necessary,

without this information medical necessity for continued use cannot be established. The requested treatment is not medically necessary.

Diclofenac 100mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAID's Page(s): 67-68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) /Diclofenac.

Decision rationale: Per the MTUS, NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. Per the ODG Diclofenac is not recommended as first line due to increased risk profile. A large systematic review of available evidence on NSAIDs confirms that diclofenac, a widely used NSAID, poses an equivalent risk of cardiovascular events to patients, as did rofecoxib (Vioxx), which was taken off the market. A review of the injured workers medical records do not show a failed trial of other recommended first line NSAIDS, therefore the request for diclofenac 100mg # 60 is not medically necessary.

Omeprazole 20mg #60: Upheld

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

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) Pain(Chronic) / Proton Pump Inhibitors.

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 reveals that he has had mild acid reflux, however the request for diclofenac has not been found to be medically necessary and therefore the prophylactic use of Omeprazole 20mg #60 is not medically necessary.