

Case Number:	CM15-0185308		
Date Assigned:	09/25/2015	Date of Injury:	05/07/2005
Decision Date:	12/02/2015	UR Denial Date:	08/30/2015
Priority:	Standard	Application Received:	09/21/2015

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 56-year-old male, who sustained an industrial injury on May 07, 2005. The injured worker was diagnosed as having status post lumbar decompression and fusion at lumbar four to five and lumbar five to sacral one, residual left lower extremity numbness, weakness, and pain to the knee area and above, anterior and posterior approach for lumbar fusion, anxiety, insomnia, residual lumbar stenosis at lumbar three to four, lumbar four to five, and lumbar five to sacral one, and residual bilateral foraminal stenosis at lumbar four to five and lumbar five to sacral one. Treatment and diagnostic studies to date has included a medication regimen and above noted procedure. In a progress note dated August 10, 2015 the treating physician reports complaints of "moderate" low back pain with difficulty sleeping. Examination performed on August 10, 2015 was revealing for stiff back with ambulation, decreased range of motion to the upper and lower back, positive straight leg raises bilaterally, "slightly" decreased sensation to the left lumbar five and sacral one region, and "slightly decreased" left lumbar five to sacral one heel walk, toe walk, extensor hallucis longus, gastrocnemius, peroneals, hamstrings, and quadriceps. On August 10, 2015 the injured worker's medication regimen included Ketoprofen cream, Gabapentin cream, Tramadol cream, Naprosyn, Tramadol, Prilosec, and Gabapentin, but the note did not indicate how long the injured worker has been on this medication regimen and the documentation provided did not indicate the injured worker's pain level as rated on a pain scale prior to the use of his regimen medication and after use of his medication regimen to indicate the effects with the use of the injured worker's medication regimen. In addition, the documentation provided did not indicate if the injured worker

experienced any functional improvement with use of his medication regimen. On August 10, 2015 the treating physician requested the medications Ketoprofen topical cream (with the quantity and strength not specified), Gabapentin topical cream (with a quantity and strength not specified), Tramadol topical cream (with a quantity and strength not specified), Naprosyn 550mg with a quantity of 60, and Prilosec 20mg with a quantity of 90 noting the current use of these medications. On August 28, 2015, the Utilization Review determined the requests for Ketoprofen topical cream (with the quantity and strength not specified), Gabapentin topical cream (with a quantity and strength not specified), Tramadol topical cream (with a quantity and strength not specified), Naprosyn 550mg with a quantity of 60, and Prilosec 20mg with a quantity of 90 to be non-certified.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen topical cream (qty and strength not specified): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

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, Ketoprofen is not FDA approved for topical use due to high incidence of photocontact dermatitis. This request is also not associated with a strength, dose and quantity; therefore, the request for Ketoprofen topical cream (qty and strength not specified) is not medically necessary.

Gabapentin topical cream (qty and strength not specified): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

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, This request is also not associated with a strength, dose and quantity, therefore the request for gabapentin topical cream (qty and strength not specified) is not medically necessary.

Tramadol topical cream (qty and strength not specified): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

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, this request is also not associated with a strength, dose and quantity, therefore the request for tramadol topical cream (qty and strength not specified) is not medically necessary.

Naprosyn 550mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs).

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 naproxen being the safest drug). There is no evidence of long-term effectiveness for pain or function. A review of the injured workers medical records that are available do not reveal documentation of pain and functional improvement with the use of this medication as required by the guidelines, without this information medical necessity is not established.

Prilosec 20mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) / Proton Pump Inhibitors (PPIs).

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 plus 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) However, a review of the injured workers medical records that are available do not reveal any current or past gastrointestinal complaints that would suggest that the injured worker is at increased risk for a gastrointestinal event therefore the request for Prilosec 20mg #90 is not medically necessary.