MAXIMUS Federal Services

Case Number:	CM15-0176493		
Date Assigned:	09/17/2015	Date of Injury:	09/07/2013
Decision Date:	11/09/2015	UR Denial Date:	08/07/2015
Priority:	Standard	Application Received:	09/08/2015

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 45 year old male, who sustained an industrial injury on September 7, 2013, resulting in pain or injury to the lumbar spine. A review of the medical records indicates that the injured worker is undergoing treatment for clinical evidence of a disc herniation of the lumbar spine. On May 8, 2015, the injured worker reported low back pain occasionally radiating with numbness and tingling to the lower extremities. The Re-Examination report dated June 22, 2015, noted the injured worker was doing poorly and continued to complain of pain. The physical examination was noted to show the injured worker in moderate distress with tenderness about the lumbar spine. X-rays of the lumbar spine and thoracic spine were noted to show loss of lumbar lordosis with soft tissue swelling. The Physician noted the injured worker's condition had changed significantly, and dispensed Hydrocodone, Diclofenac Sodium, Tramadol HCL ER, Cyclobenzaprine, and Pantoprazole Sodium. The injured worker was also noted to be given prescriptions for Norco, Orphenadrine-Caffeine prescribed since at least January 2, 2015, Gabapentin-Pyridoxine, Omeprazole-Flurbiprofen prescribed since at least January 2, 2015, Flurbiprofen-Cyclobenzaprine-Menthol cream, Keratek gel prescribed since at least November 10, 2014, and Mometasone-Doxepin cream prescribed since at least January 2, 2015. Prior treatments have included at least 36 sessions of physical therapy with some relief, 6-12 chiropractic treatments with some relief, cortisone injection to the lumbar spine in March 2015 with 20-30% relief, and medication. The injured worker was noted to be temporarily partially disabled. The request for authorization dated July 21, 2014, included retrospective requests for Orphenadrine 50 mg- Caffeine 10 mg #60, Flurbiprofen-Omeprazole 100/10 mg #60, Keratek

Gel 4oz, and Mometasone-Doxepin cream 0.15%/5% 60 gm, all for the dates of service of June 22, 2015. The Utilization Review (UR) dated August 7, 2015, denied the retrospective requests for Orphenadrine 50 mg- Caffeine 10 mg #60, Flurbiprofen-Omeprazole 100/10 mg #60, Keratek Gel 4oz, and Mometasone-Doxepin cream 0.15%/5% 60 gm, all for the dates of service of June 22, 2015.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective review for Orphenadrine 50mg/Caffeine 10mg #60 dispensed on 6/22/15: 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): Muscle relaxants (for pain).

Decision rationale: The MTUS recommends non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. (Homik, 2004) Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in patients driving motor vehicles or operating heavy machinery. Drugs with the most limited published evidence in terms of clinical effectiveness include chlorzoxazone, methocarbamol, dantrolene and baclofen. This medication is not recommended for long-term use and there are no extenuating circumstances or documentation of pain or functional improvement that warrant continued use in the injured worker, therefore the request for Retrospective review for Orphenadrine 50mg/Caffeine 10mg #60 dispensed on 6/22/15 is not medically necessary.

Retrospective review for Flurbiprofen/Omeprazole 100/10mg #60 dispensed on 6/22/15: 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 + 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 do not reveal any past or current gastrointestinal complaints that would indicate that the injured worker is at increased risk for a gastrointestinal event, there is also no rationale given for the choice of this combination of medications in the injured worker, therefore the request for Retrospective Flurbiprofen/Omeprazole 100/10mg #60 dispensed on 6/22/15 is not medically necessary.

Retrospective review for Kera Tek Gel 4 oz dispensed 6/22/15: 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, there is also no documentation of improvement in pain and function with the use of this medication therefore the request for Kera Tek Gel 4 oz dispensed 6/22/15 is not medically necessary.

Retrospective review for Mometasone/Doxepin cream 0.15% and 5%, 60gm dispensed on 6/22/22/15: 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, there is also no documentation of improvement in pain and function with the use of this medication therefore the request for Mometasone/Doxepin cream 0.15% and 5%, 60gm dispensed on 6/22/22/15 is not medically necessary.