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| Case Number: | CM15-0191202 | | |
| Date Assigned: | 10/05/2015 | Date of Injury: | 08/27/2005 |
| Decision Date: | 12/10/2015 | UR Denial Date: | 09/02/2015 |
| Priority: | Standard | Application Received: | 09/29/2015 |

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 48 year old female, who sustained an industrial injury on August 27, 2005. The injured worker was diagnosed as having low back pain, carpal tunnel syndrome, cervical facet syndrome, cervical radiculopathy, shoulder pain, and lumbar facet syndrome. Treatment and diagnostic studies to date has included laboratory studies, bilateral transforaminal epidural steroid injections times three, lumbar epidural steroid injections times one, electromyogram with nerve conduction study of the bilateral upper extremities, magnetic resonance imaging of the lumbar spine, cervical facet nerve block, cervical medial branch radiofrequency neurotomy, left sided cervical medial branch blocks, magnetic resonance arthrogram of the right shoulder, magnetic resonance imaging of the cervical spine, magnetic resonance imaging of the right shoulder, and medication regimen. In a progress note dated August 13, 2015 the treating physician reports complaints of a lower backache. Examination performed on August 13, 2015 was revealing for left sided antalgic gait, decreased range of motion to the cervical spine, tenderness to the cervical facet joints on the right side, decreased range of motion to the lumbar spine, tenderness to the bilateral paravertebral muscles, positive lumbar facet loading bilaterally, tenderness to the sacroiliac joint, decreased range of motion to the right shoulder with pain, positive Hawkin's testing, tenderness to the acromioclavicular joint and the greater tubercle of the humerus, tenderness to the medial epicondyle, tenderness to the right wrist, positive Tinel's testing bilaterally, tenderness to the left wrist, positive left Phalen's testing, tenderness to the bilateral hands, positive Finkelstein's testing to the left hand, tenderness to the left knee medial and lateral joint line, decreased sensation to the right foot and calf, and positive bilateral straight leg raises. On August 13, 2015 the injured worker's

medication regimen included Celebrex (since at least May of 2014), Prilosec (since at least May of 2014), Lyrica (since at least May of 2014), Lidoderm (since at least April of 2015), Norco (since at least May of 2014), and Ropinirole (since at least October of 2014). The injured worker's pain level on August 13, 2015 was rated an 8 on a scale of 1 to 10 with the use of her medication regimen and rates the pain a 9 on the scale of 1 to 10. The progress note from August 13, 2015 noted that prior transforaminal epidural steroid injections provided "great pain relief and moderate-great radiculopathy relief" and noted that the relief last approximately 2 to 3 months. On August 13, 2015 the treating physician requested Celebrex 200mg with a quantity of 30 with 3 refills, Prilosec DR 20mg with a quantity of 30 with 3 refills, Norco 10-325mg with a quantity of 110, and Lyrica 100mg with a quantity of 90 noting current use of these medications as indicated above. On September 02, 2015 the Utilization Review denied the requests for Celebrex 200mg with a quantity of 30 with 3 refills, Prilosec DR 20mg with a quantity of 30 with 3 refills, Norco 10-325mg with a quantity of 110, and Lyrica 100mg with a quantity of 90.

IMR ISSUES, DECISIONS AND RATIONALES

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

Celebrex 200mg #30, 3 refills: Overturned

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 rationale: Per the MTUS, NSAIDs and COX-2 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. (Chen, 2008) (Laine, 2008) 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 this, It is reported that the injured worker has nausea, heartburn and stomach upset secondary to medication use which are resolved with the use prilosec, it is also reported that the injured worker experiences improvement in inflammatory pain and is able to perform ADL's with the use of Celebrex, the continued use appears appropriate, therefore the request for Celebrex 200mg #30, 3 refills is medically necessary.

Prilosec DR 20mg #30, 3 refills: Overturned

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). It is reported that the injured worker has nausea, heartburn and stomach upset secondary to medication use which are resolved with the use of prilosec continued use is appropriate, therefore the request for Prilosec DR 20mg #30, 3 refills is medically necessary.

Norco 10/325mg #110: Overturned

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): Opioids, criteria for use.

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.

Ongoing 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. A review of the injured workers medical records reveal documentation of pain and functional improvement with the use of Norco, ongoing management actions were also addressed, continued use is appropriate, therefore the request for Norco 10/325mg #110 is medically necessary.

Lyrica 100mg #90: Overturned

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): Antiepilepsy drugs (AEDs).

Decision rationale: Per the MTUS, antiepilepsy drugs are recommended for neuropathic pain. Gabapentin is considered first line treatment for neuropathic pain. The choice of specific agents reviewed below will depend on the balance between effectiveness and adverse reactions. A "good" response to the use of AEDs has been defined as a 50% reduction in pain and a "moderate" response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the "trigger" for the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); or (2) combination therapy if treatment with a single drug agent fails. (Eisenberg, 2007) (Jensen, 2006) After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. The continued use of Lyrica is appropriate in this injured worker, with documented improvement in pain and function with its use, therefore the request for Lyrica 100mg #90 is medically necessary.