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| Case Number: | CM14-0092458 | | |
| Date Assigned: | 08/08/2014 | Date of Injury: | 06/28/2005 |
| Decision Date: | 06/11/2015 | UR Denial Date: | 06/12/2014 |
| Priority: | Standard | Application Received: | 06/19/2014 |

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: New York
 Certification(s)/Specialty: Internal 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 with an industrial injury dated 06/28/2005. His diagnoses include lumbago, status post L4-L5 posterior lumbar interbody fusion, and retained symptomatic lumbar spinal hardware. Recent diagnostic testing was not provided or discussed. He has been treated with Lumbar fusion at the L4-L5 levels (date not known), steroid injection to the lumbar spine (04/28/2014), medications, and conservative care. In a progress note dated 04/28/2014, the treating physician reports chronic symptoms in the lumbar spine. The objective examination revealed pain in the lumbosacral spine near the L5 screw, significant reproducible pain to superficial and deep palpation, and dysesthesia in the L5-S1 dermatome. The treating physician is requesting multiple medications, which were denied by the utilization review. On 06/12/2014, Utilization Review non-certified a prescription for naproxen 550mg #120, noting the lack of documented measurable decrease in pain and functional benefit with use of this medication. The MTUS Guidelines were cited. On 06/12/2014, Utilization Review non-certified a prescription for omeprazole 20mg #120, noting the non-certification of non-steroid anti-inflammatory drugs and the absence of continued gastrointestinal symptoms despite the lack of non-steroid anti-inflammatory drug use. The MTUS Guidelines were cited. On 06/12/2014, Utilization Review non-certified a prescription for ondansetron 8mg #30, noting the absence of ongoing symptoms of nausea and vomiting. The ODG Guidelines were cited. On 06/12/2014, Utilization Review non-certified a prescription for orphenadrine citrate #120, noting the lack of recommendation of long term use, and the certification of another muscle relaxant medication. The MTUS and ODG Guidelines were cited. On 06/12/2014, Utilization Review non-certified a

prescription for tramadol 150mg #90, noting the lack of documented measurable decrease in pain and functional benefit with use of this medication, and the non-compliance with medication guidelines. The MTUS Guidelines were cited. On 06/12/2014, Utilization Review non-certified a prescription for Terocin patch #30, noting the lack of documented failed trials of first line recommendations, lack of evidence to indicate an intolerance or being unresponsive to oral equivalents, and lack of evidence of unresponsiveness or intolerance to all other treatments. The MTUS Guidelines were cited. On 06/18/2014, the injured worker submitted an application for IMR for review of naproxen, omeprazole, ondansetron, orphenadrine citrate, tramadol, and Terocin patch.

IMR ISSUES, DECISIONS AND RATIONALES

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

Naproxen sodium 550mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines non-steroidal anti-inflammatory drug (NSAIDS).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67.

Decision rationale: MTUS states that Non-steroidal anti-inflammatory drugs (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. There is no evidence of long-term effectiveness for pain or function. The injured worker is diagnosed with retained symptomatic lumbar spinal hardware with complains of chronic low back pain. Documentation fails to demonstrate significant improvement in pain or level of function on current medication. With MTUS guidelines not being met, the request for Naproxen sodium 550mg #120 is not medically necessary.

Omeprazole 20mg #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68.

Decision rationale: Proton Pump Inhibitors (PPIs) are used to treat Gastrointestinal conditions such as Gastroesophageal reflux disease, Dyspepsia and Gastric ulcers, and to prevent ulcerations due to long term use of Non-steroidal anti-inflammatory drugs (NSAIDs). MTUS recommends the combination of NSAIDs and PPIs for patients at risk for gastrointestinal events, including age over 65 years of age, history of peptic ulcer, gastrointestinal bleeding, or perforation, concurrent use of ASA and high dose or multiple NSAIDs. Documentation does not support that the injured worker is at high risk of gastrointestinal events to establish the medical

necessity of ongoing use of Omeprazole. The request for Omeprazole 20mg #120 is not medically necessary.

Ondansetron 8mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines-Treatment Workers Compensation, Pain Procedure Summary last updated 05/15/2014.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Not addressed. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Medications.

Decision rationale: Ondansetron (Zofran) is FDA-approved for nausea and vomiting that may be caused by chemotherapy and radiation treatment and for postoperative use. ODG states that this medication is not recommended for nausea and vomiting secondary to chronic opioid use. Documentation fails to show evidence that the injured worker's condition fits criteria for the use of Ondansetron. The request for Ondansetron 8 mg, quantity #30 is not medically necessary per guidelines.

Orphenadrine Citrate #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63.

Decision rationale: MTUS states muscle relaxants should be used with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. The injured worker's symptoms are chronic and ongoing. Documentation shows that another muscle relaxant, Cyclobenzaprine, has been prescribed with no objective report of significant improvement in pain or level of function to support the medical necessity of Orphanadrine. With MTUS guidelines not being met, the request for Orphenadrine Citrate #120 is not medically necessary.

Tramadol 150mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Tramadol Page(s): 77, 113.

Decision rationale: MTUS recommends that ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects must be documented with the use of Opioids. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Tramadol is a centrally acting analgesic reported to be effective in managing neuropathic pain. Per MTUS guidelines, there are no long-term studies to allow use of Tramadol for longer than three months. Documentation fails to demonstrate significant improvement in pain or function, to justify the ongoing use of Tramadol. With MTUS guidelines not being met, the request for Tramadol 150mg #30 is not medically necessary.

Terocin #30: Upheld

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

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

Decision rationale: MTUS states that use of topical analgesics is primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of many of these agents. Terocin is a topical analgesic containing Lidocaine and Menthol. MTUS provides no evidence recommending the use of topical Menthol. Per guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The request for Terocin #30 is not medically necessary.