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| Case Number: | CM15-0091281 | | |
| Date Assigned: | 05/19/2015 | Date of Injury: | 07/15/2003 |
| Decision Date: | 09/22/2015 | UR Denial Date: | 04/21/2015 |
| Priority: | Standard | Application Received: | 05/12/2015 |

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: California
 Certification(s)/Specialty: Emergency 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 59 year old male who sustained an industrial injury on July 15, 2003. Previous treatment includes medications. Currently the injured worker complains of an increase in low back pain and bilateral leg radiculopathy as well as an increase in nausea and loss of bladder control. His symptoms are limiting his tolerance to exercise and physical activities. He reports that he is functional with his medications. On physical examination he has moderate paralumbar and thoracocervical myospasm. Diagnoses associated with the request include lumbar disc disease with myelopathy, radiculopathy, and urinary incontinence. The treatment plan includes Trazodone #60, Methadone #180, Provigil #30, Pepcid #30, Flector #30, Gabapentin #180, Oxycontin #60, Percocet #120, Xanax #50 and Nabumetone #60.

IMR ISSUES, DECISIONS AND RATIONALES

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

Trazodone 50mg #60 x 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Official Disability Guidelines, Mental Illness and Stress.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Stress, Trazodone.

Decision rationale: The request is for the use of the medication trazodone. This is a medication in the category of a serotonin agonist and reuptake inhibitor and is used for depression. It also has anxiolytic and sedative hypnotic effects. The MTUS guidelines are silent regarding its use. The ODG guidelines state that this medication is indicated as an option for insomnia for patients with coexisting depression or anxiety. Its use as a first-line treatment for primary insomnia is not advised. Evidence for the off-label use of trazodone for treatment of insomnia is poor. The current recommendation is to use a combined pharmacologic and psychological and behavior treatment when primary insomnia is diagnosed. In this case, there is inadequate documentation of a psychiatric evaluation revealing co-morbid factors which would qualify the patient for use of trazodone as a first-line agent. As such, the request is not medically necessary.

Methadone 10mg #180: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78 of 127.

Decision rationale: The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. In this case, there is inadequate documentation of persistent functional improvement which should eventually lead to medication discontinuation. The records also do not reveal screening measures as discussed above for continued use of a medication in the opioid class. As such, the request is not medically necessary. All opioid medications should be titrated down slowly in order to prevent a significant withdrawal syndrome.

Provigil 200mg #30 x 1 refill: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Provigil.

Decision rationale: The request is for the medication Provigil. The MTUS guidelines are silent regarding this topic. The ODG state the following: Not recommended solely to counteract

sedation effects of narcotics until after first considering reducing excessive narcotic prescribing. Use with caution as indicated below. Indications: Provigil is indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea, and shift work sleep disorder. Patients should have a complete evaluation with a diagnosis made in accordance with the International Classification of Sleep Disorders or DSM diagnostic classification. Adverse effects: This drug has been known to be misused and/or abused, particularly by patients that have a history of drug or stimulant abuse. Common adverse effects include headache, nausea, nervousness, rhinitis, diarrhea, back pain, anxiety, insomnia, dizziness, and dyspepsia. Dose: The standard dose for these conditions is 200 mg a day. The dose should be reduced to for patients with severe hepatic impairment. (Clinical Pharmacology, 2008) (Micromedex, 2008) (Lexi-Comp, 2008) (AHFS Drug Information, 2008) Modafinil is increasingly being used as a cognitive enhancer. Although initially launched as distinct from stimulants that increase extracellular dopamine by targeting dopamine transporters, recent preclinical studies suggest otherwise. There is need for heightened awareness for potential abuse of and dependence on modafinil. (Kumar, 2008) (Volkow-JAMA, 2009) Prescriptions for modafinil have rapidly increased in recent years, and most of this increase is due to off-label use, according to a JAMA study, with 89% of patients prescribed modafinil not having an on-label diagnosis. The company that markets modafinil, ██████████, was sued by several US states for promoting modafinil for off-label indications and agreed to a settlement in 2008. (Pealoza, 2013) In this case, the use of Provigil is not indicated. This is secondary to inadequate documentation of a condition which would qualify for its use. As such, the request is not medically necessary.

Pepcid 40mg #30 x 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms and Cardiovascular Risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines
Page(s): 68 of 127.

Decision rationale: The request is for the use of a medication in the class of an acid reducing medication. The guidelines do not specifically address or advise the use of an H2 blocker but does make recommendations regarding medications in the same category classified as proton pump inhibitors. This is usually given for patients with esophageal reflux, gastritis, or peptic ulcer disease. It can also be used as a preventative measure in patients taking non-steroidal anti-inflammatories for chronic pain which have side effects including gastrointestinal disease. The MTUS guidelines states that patients who are classified as intermediate or high risk, should be treated prophylactically with a proton pump inhibitor or Misoprostol. Criteria for risk are as follows: "(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)." Due to the fact the patient does not meet to above stated criteria, the request for use is not medically necessary.

Flector patch 1.3% #30 x 2 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-112 of 127.

Decision rationale: The request is for the use of a topical NSAID for pain relief. There are specific criteria require for use based on the guidelines. The MTUS states the following: The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. In this case, as indicated above, the patient would not qualify for the use of this medication based on the diagnosis and treatment duration. As such, the request is not medically necessary.

Gabapentin 300mg #180: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 16-17 of 127.

Decision rationale: The request is for the use of a medication in the category of an anti-epileptic drug (AED). These medications are recommended for certain types of neuropathic pain. Most of the randomized clinical control trials involved include post-herpetic neuralgia and painful polyneuropathy such as in diabetes. There are few trials which have studied central pain or radiculopathy. The MTUS guidelines state that a good response to treatment is 50% reduction in pain. At least a 30% reduction in pain is required for ongoing use, and if this is not seen, this should trigger a change in therapy. Their also should be documentation of functional improvement and side effects incurred with use. Disease states which prompt use of these medications include post-herpetic neuralgia, spinal cord injury, chronic regional pain syndrome, lumbar spinal stenosis, post-operative pain, and central pain. There is inadequate evidence to support use in non-specific axial low back pain or myofascial pain. In this case, the records also do not reveal functional improvement or screening measures as required to justify continued use. As such, the request is not medically necessary.

Oxycontin ER 30mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78 of 127.

Decision rationale: The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. In this case, there is inadequate documentation of persistent functional improvement which should eventually lead to medication discontinuation. The records also do not reveal screening measures as discussed above for continued use of a medication in the opioid class. As such, the request is not medically necessary. All opioid medications should be titrated down slowly in order to prevent a significant withdrawal syndrome.

Percocet 10/325mg #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78 of 127.

Decision rationale: The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. In this case, there is inadequate documentation of persistent functional improvement which should eventually lead to medication discontinuation. The records also do not reveal screening measures as discussed above for continued use of a medication in the opioid class. As such, the request is not medically necessary. All opioid medications should be titrated down slowly in order to prevent a significant withdrawal syndrome.