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| Case Number: | CM15-0186455 | | |
| Date Assigned: | 09/28/2015 | Date of Injury: | 06/02/2014 |
| Decision Date: | 11/24/2015 | UR Denial Date: | 08/24/2015 |
| Priority: | Standard | Application Received: | 09/22/2015 |

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 49-year-old male, with a reported date of injury of 06-02-2014. The diagnoses include low back pain, bilateral sacroiliac joint dysfunction, chronic pain syndrome, muscle spasm, and high blood pressure. Treatments and evaluation to date have included acupuncture, Lidopro patches (since at least 05-2015), Pamelor, Naproxen (since at least 07-2015), Omeprazole (since at least 07-2015), Lunesta, Flexeril (since at least 05-2015), TENS unit, physical therapy, and a sacroiliac belt. The diagnostic studies to date have not been included in the medical records. The progress report dated 08-12-2015 indicates that the injured worker denied any changes in the signs and symptoms, and continued to report low back pain with radiation to the bilateral lower extremities, right greater than left with noted paresthesias. The injured worker rated his pain 5 out of 10; and on 07-15-2015, the injured worker rated his pain 6 out of 10. He also reported weakness going up the stairs. The objective findings include tenderness to palpation of the lumbar paraspinal muscles and decreased lumbar range of motion. The treatment plan included a refill of Naproxen, Omeprazole, Lunesta, Flexeril, Lidopro topical cream, and six follow-up visits. The request for authorization was dated 08-12-2015. The treating physician requested Lunesta mg, Flexeril 7.5mg, Lidopro topical cream, six follow-up visits, Omeprazole 20mg, and Naproxen 550mg. On 08-24-2015, Utilization Review (UR) non-certified the request for Lunesta mg, Flexeril 7.5mg, Lidopro topical cream, Omeprazole 20mg, and Naproxen 550mg; and modified the request for six follow-up visits to one follow-up visit.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lunesta 1 mg: Upheld

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

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)/Insomnia Treatment.

Decision rationale: The request is for the use of a medication used for insomnia. The Official Disability Guidelines state the following regarding this topic: Recommend that treatment be based on the etiology, with the medications recommended below. See also Insomnia. For more detail on Insomnia treatment, see the Mental Chapter. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. (Lexi-Comp, 2008) Primary insomnia is generally addressed pharmacologically. Secondary insomnia may be treated with pharmacological and/or psychological measures. The specific component of insomnia should be addressed: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; & (d) Next-day functioning. In this case, the use of this medication is not recommended. This is secondary to inadequate documentation of a thorough evaluation of the etiology or attempted non-pharmacologic restorative measures undertaken. As such, the request is not certified.

Flexeril 7.5 mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

Decision rationale: The request is for the use of a muscle relaxant to aid in pain relief. The MTUS guidelines state that the use of a medication in this class is indicated as a second-line option for short-term treatment of acute exacerbations of low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, which can increase mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain improvement. Efficacy appears to diminish over time, and prolonged use may lead to dependence. (Homik, 2004) Due to inadequate documentation of a recent acute exacerbation and poor effectiveness for chronic long-term use, the request is not certified.

Lidopro topical cream: 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: The request is for the use of topical lidocaine. The MTUS guidelines state the following: Lidocaine Indication: Neuropathic pain: Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. In this case, as stated above, the patient does not meet the criteria for use of this product in this formulation. There is a requirement of documentation of a first-line therapy trial prior to use of a lidocaine dermal patch. There is also no other commercially approved topical formulations of lidocaine indicated for neuropathic pain other than Lidoderm. As such, the request is not certified.

Six follow-up visits: Upheld

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

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)/Office Visits.

Decision rationale: The request is for a pain management consultation. The MTUS guidelines do not address this issue specifically. The ODG state the following regarding this topic. Recommended as determined to be medically necessary. Evaluation and management (E&M) outpatient visits to the offices of medical doctor(s) play a critical role in the proper diagnosis and return to function of an injured worker, and they should be encouraged. The need for a clinical office visit with a health care provider is individualized based upon a review of the patient concerns, signs and symptoms, clinical stability, and reasonable physician judgment. The determination is also based on what medications the patient is taking, since some medicines such as opiates, or medicines such as certain antibiotics, require close monitoring. As patient conditions are extremely varied, a set number of office visits per condition cannot be reasonably established. The determination of necessity for an office visit requires individualized case review and assessment, being ever mindful that the best patient outcomes are achieved with eventual patient independence from the health care system through self care as soon as clinically feasible. The ODG Codes for Automated Approval (CAA), designed to automate claims management decision-making, indicates the number of E&M office visits (codes 99201-99285) reflecting the typical number of E&M encounters for a diagnosis, but this is not intended to limit or cap the number of E&M encounters that are medically necessary for a particular patient. Office visits that exceed the number of office visits listed in the CAA may serve as a "flag" to payors for possible evaluation, however, payors should not automatically deny payment for these if preauthorization has not been obtained. Note: The high quality medical studies

required for treatment guidelines such as ODG provides guidance about specific treatments and diagnostic procedures, but not about the recommended number of E&M office visits. Studies have and are being conducted as to the value of "virtual visits" compared with inpatient visits, however the value of patient/doctor interventions has not been questioned. (Dixon, 2008) (Wallace, 2004) Further, ODG does provide guidance for therapeutic office visits not included among the E&M codes, for example Chiropractic manipulation and Physical/Occupational therapy. See also [REDACTED] In this case, the request is reasonable and supported by the documentation. The patient has chronic pain, which justifies ongoing visits for monitoring. At issue is the number of visits requested. As such, the request is not certified due to the excessive number of visits requested.

Omeprazole 20 mg: 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 rationale: The request is for the use of a medication in the class of a proton pump inhibitor. It is indicated for patients with peptic ulcer disease. It can also be used as a preventative measure in patients taking non-steroidal anti-inflammatories for chronic pain. Unfortunately, they do have certain side effects including gastrointestinal disease. The MTUS guidelines states that patients who are classified as intermediate or high risk, should be treated prophylactically. 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 certified.

Naproxen 550 mg: Upheld

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

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)/NSAIDs (non-steroidal anti-inflammatory drugs).

Decision rationale: The request is for the use of a medication in the NSAID class. The ODG state the following regarding this topic: Specific recommendations: Osteoarthritis (including knee and hip): 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 naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. (Chen, 2008) (Laine, 2008) Back Pain - Acute low back pain & acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting to negative evidence that NSAIDs are more effective than acetaminophen for acute LBP. (van Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. (Hancock, 2007) Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another. (Roelofs-Cochrane, 2008) See also Anti-inflammatory medications. Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in patients with neuropathic pain. (Namaka, 2004) (Gore, 2006) See NSAIDs, GI symptoms & cardiovascular risk; NSAIDs, hypertension and renal function; & Medications for acute pain (analgesics). Besides the above well-documented side effects of NSAIDs, there are other less well-known effects of NSAIDs, and the use of NSAIDs has been shown to possibly delay and hamper healing in all the soft tissues, including muscles, ligaments, tendons, and cartilage. (Maroon, 2006) The risks of NSAIDs in older patients, which include increased cardiovascular risk and gastrointestinal toxicity, may outweigh the benefits of these medications. (AGS, 2009) As stated above, acetaminophen would be considered first-line treatment for chronic pain. In this case, the continued use of an NSAID is not supported. This is secondary to inadequate documentation of functional improvement benefit seen. Also, the duration of use places the patient at risk for gastrointestinal and cardiovascular side-effects. In addition, it is known that use of NSAIDs delays the healing of soft tissue including ligaments, tendons, and cartilage. As such, the request is not certified.