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| Case Number: | CM14-0171195 | | |
| Date Assigned: | 10/23/2014 | Date of Injury: | 05/21/2003 |
| Decision Date: | 11/21/2014 | UR Denial Date: | 10/01/2014 |
| Priority: | Standard | Application Received: | 10/16/2014 |

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. The expert reviewer is Board Certified in Family Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 patient is a 58 year-old man who was injured at work on 5/21/2003. The injury was primarily to his neck, both arms and the lower back. He is requesting review of denial for the following: Lidoderm 5% Patch #30 with 1 Refill, Trazodone 100mg #30 with 1 Refill and Vicodin 5/300mg #90 with 1 Refill. Medical records corroborate ongoing care for his injuries. His chronic diagnoses include the following: Lumbar Radiculopathy; Diabetes Mellitus; Gastritis/Medication Related Dyspepsia; and Chronic Pain/Other. Pharmacologic treatment has included opioids, topical analgesics (containing either NSAIDs or lidocaine) and Trazodone (for chronic insomnia).

IMR ISSUES, DECISIONS AND RATIONALES

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

1 prescription of Lidoderm 5% patch #30 with 1 refill: Upheld

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

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

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of topical analgesics, including lidocaine. In general, use of topical analgesics is considered

as largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. There is little to no research to support the use of many of these agents. Comments from the guidelines regarding lidocaine are as follows: 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. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. In February 2007 the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical lidocaine. Those at particular risk were individuals that applied large amounts of this substance over large areas, left the products on for long periods of time, or used the agent with occlusive dressings. Systemic exposure was highly variable among patients. Only FDA-approved products are currently recommended. (Argoff, 2006) (Dworkin, 2007) (Khaliq-Cochrane, 2007) (Knotkova, 2007) (Lexi-Comp, 2008) Non-neuropathic pain: Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. (Scudds, 1995) In this case it is unclear whether topical lidocaine is intended for neuropathic or non-neuropathic pain, based on a review of the medical records. If it was intended for neuropathic pain, the guidelines do not support its current use as there is insufficient evidence that the patient had received adequate trials of either antidepressants or anti-epilepsy drugs. If it was intended for non-neuropathic pain, then it is not a recommended treatment. In summary, there is insufficient information in support of the use of topical lidocaine in this patient. A Lidoderm 5% Patch is not considered as a medically necessary treatment.

1 prescription of Trazadone 100mg #30 with 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 (ODG), Mental Illness & Stress

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

Decision rationale: The Official Disability Guidelines (ODG) comment on the treatment of insomnia for patients with chronic pain. In general these guidelines recommend the following approach to the patient with insomnia: They recommend that the treating physician define the nature of the sleep disturbance. Specifically, is the difficulty in sleep initiation or maintenance, and/or early awakening. There should be an assessment of impairment in daily function due to

sleep insufficiency. These impairments include fatigue, irritability, decreased memory, decreased concentration, and malaise. They recommend that the insomnia be classified in the following manner: (1) Based on symptoms: Categories of symptoms include sleep onset, sleep maintenance, non-restorative sleep. These symptoms have been found to change over time. (2) Based on duration: (a) Acute insomnia (transient insomnia): Usually the result of specific environmental or social events. Generally treated by addressing the episode directly (death of a family member, working on a different shift, travel), or prophylactically. (b) Chronic insomnia: Generally defined as lasting more than one month. This condition may be correlated with other intrinsic sleep disorders, primary insomnia, or chronic medical conditions. Chronic insomnia is more likely to occur in the elderly, depressed patients, and medically ill populations. (3) Based on etiology: (a) Primary insomnia: No known physical or mental condition is noted as an etiology. This condition is generally consistent and responsive to treatment. (b) Secondary insomnia (comorbid insomnia): insomnia that is secondary to other medical and psychiatric illnesses, medications, or sleep disorders. Examples include chronic pain, gastroesophageal reflux disease (GERD), heart failure, end-stage renal disease, diabetes, neurologic problems, psychiatric disorders, and certain medications. Diabetic patients appear to suffer insomnia due to alterations of circadian rhythm. They may also suffer from sleep disorders related to obesity. Psychiatric disorders associated with insomnia include depression, anxiety and alcoholism. (Reeder, 2007) (Benca, 2005) Poor or insufficient sleep is the strongest predictor for pain in adults over 50. Among factors associated with new-onset pain were: age (OR 0.97); baseline pain status (OR 1.1); anxiety (OR 1.5); physical health-related quality of life (OR 1.3); cognitive complaint (OR 1.3); & nonrestorative sleep (OR 1.9; 95% CI 1.2 - 2.8). This study points to the need to address underlying sleep problems to bring pain relief. The ODG also recommend that treatment be based on the etiology, with the medications recommended below. 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. Sedating antidepressants, including trazodone, have also been used to treat insomnia; however, there is less evidence to support their use for insomnia, but they may be an option in patients with coexisting depression. Trazodone is one of the most commonly prescribed agents for insomnia. Side effects of this drug include nausea, dry mouth, constipation, drowsiness, and headache. Improvements in sleep onset may be offset by negative next-day effects such as ease of awakening. Tolerance may develop and rebound insomnia has been found after discontinuation. Finally, the ODG recommend use of non-pharmacologic treatments for insomnia. Empirically supported treatment includes stimulus control, progressive muscle relaxation, and paradoxical intention. Treatments that are thought to probably be efficacious include sleep restriction, biofeedback, and multifaceted cognitive behavioral therapy. Suggestions for improved sleep hygiene: (a) Wake at the same time everyday; (b) Maintain a consistent bedtime; (c) Exercise regularly (not within 2 to 4 hours of bedtime); (d) Perform relaxing activities before bedtime; (e) Keep your bedroom quiet and cool; (f) Do not watch the clock; (g) Avoid caffeine and nicotine for at least six hours before bed; (h) Only drink in moderation; & (i) Avoid napping. In this case, there is insufficient documentation to characterize the nature of this patient's sleep disturbance and its classification per the above ODG recommendations. There is insufficient documentation that the patient has undergone an evaluation of the potential causes of sleep disturbance. There is insufficient documentation that there has been an ongoing assessment of the effectiveness of trazodone on the sleep disturbance

and the patient's pain control and ability to function. There is insufficient documentation that the patient has received guidance on non-pharmacologic treatments for insomnia. In summary, there is insufficient support for the use of trazodone in this patient. Trazodone is not medically necessary.

1 prescription of Vicodin 5/300mg #90 with 1 refill: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76-78,80.

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the long-term use of opioids. These guidelines have established criteria on the use of opioids for the ongoing management of pain. Actions should include: prescriptions from a single practitioner and from a single pharmacy. The lowest possible dose should be prescribed to improve pain and function. There should be an ongoing review and documentation of pain relief, functional status, appropriate medication use and side effects. Pain assessment should include: current pain, the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. There should be evidence of documentation of the "4 A's for Ongoing Monitoring." These four domains include: pain relief, side effects, physical and psychological functioning, and the occurrence of any potentially aberrant drug-related behaviors. Further, there should be consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain that does not improve on opioids in 3 months. There should be consideration of an addiction medicine consult if there is evidence of substance misuse (Pages 76-78). Finally, the guidelines indicate that for chronic back pain, the long-term efficacy of opioids is unclear. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy (Page 80). Based on the review of the medical records, there is insufficient documentation in support of these stated MTUS/Chronic Pain Medical Treatment Guidelines for the ongoing use of opioids. There is insufficient documentation of the "4 A's for Ongoing Monitoring." The treatment course of opioids in this patient has extended well beyond the timeframe required for a reassessment of therapy. In summary, there is insufficient documentation to support the chronic use of an opioid in this patient. Treatment with Vicodin is not considered as medically necessary.

