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| Case Number: | CM14-0053152 | | |
| Date Assigned: | 08/08/2014 | Date of Injury: | 05/11/2012 |
| Decision Date: | 09/11/2014 | UR Denial Date: | 04/17/2014 |
| Priority: | Standard | Application Received: | 04/21/2014 |

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 Anesthesiology, has a subspecialty in Pain Medicine and is licensed to practice in Massachusetts. 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:

According to the documents available for review, the patient is a 35 year old with the date of injury of May 11, 2012. The mechanism of injury was not discussed in the documents available for review. The patient has been diagnosed with the thoracic outlet compression syndrome. Patient has pain in the neck and upper extremities. The patient is on a multimodal pain medication regimen consisting of Maxalt, Frova, trazodone, Topamax, tizanidine and hydrocodone. A request was for Maxalt, Frova, trazodone, Topamax, tizanidine and hydrocodone denied.

IMR ISSUES, DECISIONS AND RATIONALES

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

Hydrocodone 5/500mg #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, On-Going Management, p 74-97 Page(s): 74-97.

Decision rationale: According to the MTUS Chronic Pain Medical Treatment Guidelines section on Opioids, On-Going Management, p 74-97, (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose

should be prescribed to improve pain and function.(c) Office: 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. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) (d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management. (e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control.(f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion).(g) Continuing review of overall situation with regard to nonopioid means of pain control. (h) 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 does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Additionally, the MTUS states that continued use of opioids requires (a) the patient has returned to work, (b) the patient has improved functioning and pain. There is no current documentation of baseline pain, pain score with use of opioids, functional improvement on current regimen, side effects. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

Maxalt 10mg #9: Upheld

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

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

Decision rationale: According to the ODG, Maxalt is approved for the treatment of migraine headaches. According to the documents available for review, there is no indication that the patient suffers from migraine headaches and there is no description of pain relief or functional benefit with the use of the medication nor description of alternative or more conservative medications that have been tried. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

Frova 2.5mg #20: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2515913>.

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

Decision rationale: According to the ODG triptans are approved for the treatment of migraine. According to the documents available for review, there is no indication that the patient suffers from migraine headaches and there is no description of pain relief or functional benefit with the use of the medication nor description of alternative or more conservative medications that have been tried. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

Trazodone 50mg #75: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines - Mental Illness And Stress Trazodone.

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

Decision rationale: Recommended as an option for insomnia, only for patients with potentially coexisting mild psychiatric symptoms such as depression or anxiety. See also Insomnia treatment, where it says there is limited evidence to support its use for insomnia, but it may be an option in patients with coexisting depression. Evidence for the off-label use of trazodone for treatment of insomnia is weak. The current recommendation is to utilize a combined pharmacologic and psychological and behavior treatment when primary insomnia is diagnosed. Also worth noting, there has been no dose-finding study performed to assess the dose of trazodone for insomnia in non-depressed patients. Other pharmacologic therapies should be recommended for primary insomnia before considering trazodone, especially if the insomnia is not accompanied by comorbid depression or recurrent treatment failure. There is no clear-cut evidence to recommend trazodone first line to treat primary insomnia. According to the documents available for review, there is no description of pain relief or functional benefit with the use of the medication nor is there a description of alternative or more conservative medications that have been tried. Further, the patient has no documented history of depression. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

Topomax 25 mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines AEDs Page(s): 21.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs), Topiramate, p21 Page(s): 21.

Decision rationale: According to the MTUS, Chronic Pain Medical Treatment Guidelines, Topiramate has been shown to have variable efficacy, with failure to demonstrate efficacy in neuropathic pain of "central" etiology. It is still considered for use for neuropathic pain when other anticonvulsants fail. Topiramate has recently been investigated as an adjunct treatment for obesity, but the side effect profile limits its use in this regard. (Rosenstock, 2007) According to the documents available for review, there is no indication that other neuropathic agents have been tried and failed and there is no description of pain relief or functional benefit with the use of the medication nor description of alternative or more conservative medications that have been tried. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

Tizanidine 4mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antispasticity Page(s): 66.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antispasticity / Antispasmodic Drugs, Zanaflex, p 63-66 Page(s): 63-66.

Decision rationale: According to the MTUS, Tizanidine (Zanaflex, generic available) is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for lowback pain. (Malanga, 2008) Eight studies have demonstrated efficacy for low back pain. (Chou, 2007) One study (conducted only in females) demonstrated a significant decrease in pain associated with chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain. (Malanga, 2002) May also provide benefit as an adjunct treatment for fibromyalgia. (ICSI, 2007) Side effects: somnolence, dizziness, dry mouth, hypotension, weakness, hepatotoxicity (LFTs should be monitored baseline, 1, 3, and 6 months). (See, 2008) Dosing: 4 mg initial dose; titrate gradually by 2 - 4 mg every 6 - 8 hours until therapeutic effect with tolerable side-effects; maximum 36 mg per day. (See, 2008) Use with caution in renal impairment; should be avoided in hepatic impairment. Tizanidine use has been associated with hepatic aminotransaminase elevations that are usually asymptomatic and reversible with discontinuation. However, according to the MTUS, Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (VanTulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in patients driving motor vehicles or operating heavy machinery. Drugs with the most limited published evidence in terms of clinical effectiveness include chlorzoxazone,

methocarbamol, dantrolene and baclofen. (Chou, 2004) According to a recent review in American Family Physician, skeletal muscle relaxants are the most widely prescribed drug class for musculoskeletal conditions (18.5% of prescriptions), and the most commonly prescribed antispasmodic agents are carisoprodol, cyclobenzaprine, metaxalone, and methocarbamol, but despite their popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. (See2, 2008)According to the documents available for review, there is no documented indication that the patient has spasticity or acute muscle spasm and there is no description of pain relief or functional benefit with the use of the medication nor description of alternative or more conservative medications that have been tried. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.