MAXIMUS Federal Services

Case Number:	CM14-0174825		
Date Assigned:	10/28/2014	Date of Injury:	02/09/2010
Decision Date:	12/04/2014	UR Denial Date:	10/08/2014
Priority:	Standard	Application Received:	10/22/2014

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 56 year-old woman who was injured at work on 2/9/2010. The injury was primarily to her neck and her right shoulder/arm/wrist. She is requesting review of denial for the following medications: Tramadol ER 150mg, Take 1 Tablet QD, Naproxen 550mg, Take 1 Tablet BID, and Flexeril 7.5mg, Take 1 Tablet TID. Medical records corroborate ongoing care for her injuries. Her chronic diagnoses include: Chronic Pain Syndrome; Cervical Radiculopathy; Neck Pain; Shoulder Pain; Spinal Enthesopathy; Fasciitis (unspecified); and Lower Back Pain. The patient's chronic medication regimen includes the following: Tramadol ER, Naproxen, Flexeril, and Topical Analgesic Creams. In the assessment of the 7/15/2014 visit, the provider states the following: "Patient has failed multiple conservative therapies including physical therapy, NSAID, TENs, and various medication trials for greater than 6 months without benefit."

IMR ISSUES, DECISIONS AND RATIONALES

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

Tramadol ER 150mg , take 1 tab qd: Upheld

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

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

Decision rationale: 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 time frame 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 Tramadol ER is not considered as medically necessary.

Naproxen 550mg, take 1 tab bid: 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 NSAIDs Page(s): 67-68.

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of NSAIDs.In general, this class of medication is recommended to be used "at the lowest dose for the shortest period" and for "acute exacerbations of chronic pain."The MTUS Guidelines provide specific recommendations for different conditions.For: 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 exacerbations of chronic pain: Recommended as a second-line treatment afteracetaminophen. In general, there is conflicting evidence that NSAIDs are more effective that 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)For: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. For: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 and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain. (Namaka, 2004) (Gore, 2006) See NSAIDs, GI symptoms & cardiovascular risk; NSAIDs, hypertension and renal function. 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)In this case, the records indicate that this patient's use of NSAIDs is well beyond the time frame recommended by the above guidelines. Specifically, that Naproxen is intended for daily use and not for the acute exacerbation of chronic pain. Therefore, the use of Naproxen is not considered as medically necessary.

Flexeril 7.5mg, take 1 tab tid: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 67.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain) Page(s): 63-66.

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of muscle relaxants, such as Cyclobenzaprine (also known as Flexeril), for pain.These guidelines state the following:Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. 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. Cyclobenzaprine is categorized as an antispasmodic. The guidelines state that it is recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Specifically, "this medication is not recommended to be used for longer than 2-3 weeks."In this case, the records indicate that this patient has been on long-term use of muscle relaxants well beyond the MTUS recommendations. Therefore, the use of Cyclobenzaprine is not considered as medically necessary.