

Case Number:	CM14-0164880		
Date Assigned:	10/09/2014	Date of Injury:	02/01/2009
Decision Date:	11/10/2014	UR Denial Date:	09/08/2014
Priority:	Standard	Application Received:	10/06/2014

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 Occupational 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 claimant was injured on 02/01/09. Trazodone, Percocet, Savella, Valium, Lyrica, and Fiorinal are under review. Diagnoses include cervical strain, thoracic strain, left carpal tunnel syndrome, severe degenerative disc disease, and depression. On 03/12/14, the claimant was evaluated for pain on the left side of his neck that radiated to the left arm. It had been present for 5 years and was dull, aching and burning. It was better with rest and support of the head. He had tried rest, heat, and anti-inflammatory medications with no improvement. He attended physical therapy. Electrodiagnostic studies demonstrated left carpal tunnel syndrome and he underwent decompression. He also had surgery for left hand tendinitis. He had an MRI that showed degeneration of the disks at C4-5 and C5-6 with early degeneration at C6-7. There were disc osteophytes present, most notably at C5-C6 with bilateral foramen narrowing. At C4-5 there was minimal narrowing of the neural foramen and at C6-7 there was some narrowing of the foramina. There was no evidence of cord compression. He did not want to have surgery which would involve disc excision and fusion. Electrodiagnostic studies did not demonstrate cervical radiculopathy. He had been receiving acupuncture. The intensity of his neck pain had been increasing. His medications included Fioricet with codeine, oxycodone/acetaminophen, and Lyrica. He had limited range of motion with increased neck pain. There was some weakness of left hand grip strength. There was no objective motor weakness. Repeat EMG and nerve conduction studies and CT scan of the cervical spine were recommended. He has received multiple medications over the years. On 04/28/14, he was evaluated. There was a handwritten note that is essentially illegible. There is some mention of trigger point injections. He had been out of medications for 2 weeks. On 05/19/14, the EMG/NCV was awaited. Again the handwritten notes are nearly illegible. He received prescriptions for trazodone, Percocet, Fiorinal, Valium, and Lyrica. EMG nerve conduction study dated 05/29/14 did not show

cervical radiculopathy but there was mild right carpal tunnel syndrome. He received refills of the medications on 06/02/14. There were refilled again on 06/30/14 but again they handwritten notes are essentially illegible. He has received the medications approximately monthly.

IMR ISSUES, DECISIONS AND RATIONALES

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

Trazadone 100mg #60: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG): Formulary - Trazodone for insomnia/depression

Decision rationale: The history and documentation do not objectively support the request for Trazodone 100 mg #60. The MTUS do not address its use and the ODG state that Trazodone is "recommended as an option for insomnia, only for patients with potentially coexisting mild psychiatric symptoms such as depression or anxiety. Recommended as an option for insomnia, only for patients with potentially coexisting mild psychiatric symptoms such as depression or anxiety. There is limited evidence to support its use for insomnia, but it may be an option in patients with coexisting depression. Trazodone has been used successfully in fibromyalgia. Trazodone was approved in 1982 for the treatment of depression. It is unrelated to tricyclic or tetracyclic antidepressants and has some action as an anxiolytic. Off-label uses include alcoholism, anxiety, insomnia, and panic disorder. Although approved to treat depression, the American Psychiatric Association notes that it is not typically used for major depressive disorder. Over the period 1987 through 1996, prescribing Trazodone for depression decreased throughout the decade, while off-label use of the drug for insomnia increased steadily until it was the most frequently prescribed insomnia agent. To date, there has been only one randomized, double blind, placebo-controlled trial studying Trazodone in primary insomnia. It was observed that relative to placebo, patients reported significant improvement in subjective sleep latency, sleep duration, wake time after sleep onset, and sleep quality with Trazodone and Zolpidem during week one, but during week two the Trazodone group did not differ significantly from the placebo group whereas the Zolpidem group demonstrated significant improvement compared to placebo for sleep latency and sleep duration. (Walsh, 1998) The AHRQ Comparative Effectiveness Research on insomnia concludes that Trazodone is equal to Zolpidem. (AHRQ, 2008) 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." There is no clear evidence of depression or anxiety for which this medication appears to have been provided to him. There is no clear documentation of insomnia

associated with depression in the records. The specific indication for the use of this medication is not described in the records and none can be ascertained from the records. The medical necessity of the use of Trazodone 100 mg has not been clearly demonstrated.

Percocet 10/325mg #150: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for Chronic Pain Page(s): 110.

Decision rationale: The history and documentation do not objectively support the request for the opioid, Percocet 10/325 mg #150. The MTUS outlines several components of initiating and continuing opioid treatment and states "a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals." In these records, there is no documentation of trials and subsequent failure of or intolerance to first-line drugs such as acetaminophen or nonsteroidal anti-inflammatory drugs. There is also no indication that periodic monitoring of the claimant's pattern of use and a response to this medication, including assessment of pain relief and functional benefit, has been or will be done. Additionally, the 4A's "analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors" should be followed and documented per the guidelines. The claimant's pattern of use of Percocet and specific measurable objective or functional benefit to him are unclear. There is no evidence that a signed pain agreement is on file at the provider's office and no evidence that a pain diary has been recommended and is being kept by the claimant and reviewed by the prescriber. There is no evidence that the claimant has been involved in an ongoing exercise program to try to maintain any benefit he gets from treatment measures. As such, the medical necessity of the use of Percocet 10/325 mg #150 has not been clearly demonstrated.

Valium 10mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepine Page(s): 54.

Decision rationale: The history and documentation do not objectively support the request for Valium 10 #60. The MTUS state "benzodiazepines (alprazolam) are not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more

appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. (Baillargeon, 2003) (Ashton, 2005)" In this case, the indication for the use of Valium has not been clearly described in the records and none can be ascertained from the records. There is no clear evidence of significant anxiety or clinical evidence of spasms that have not responded to other first line medications, local modalities, and exercise. The claimant's pattern of use of Valium and the specific measurable objective or functional benefit to the claimant from the use of this medication are not clear. The medical necessity of the use of this medication has not been demonstrated.

Lyrica 150mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines anti-epilepsy drugs (AEDs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lyrica (pregabalin), Medications for Chronic Pain Page(s): 131;94.

Decision rationale: The history and documentation do not objectively support the request for the use of Lyrica 150 mg #60. The MTUS state "pregabalin (Lyrica) has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. Pregabalin was also approved to treat fibromyalgia." Also, before prescribing any medication for pain, the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication to be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medication should show effects within 1 to 3 days, ... A record of pain and function with the medication should be recorded. (Mens 2005)" In this case, none of these conditions (diabetic neuropathy, postherpetic neuralgia, or fibromyalgia) appear to be under treatment. The specific benefit to the claimant of this medication has not been described and none can be ascertained from the file. His pattern of use and functional benefit from this medication are unknown. There is no evidence of trials of other first line drugs such as gabapentin for neuropathic pain and it is not clear why Lyrica is being used. The medical necessity of use of Lyrica 150 mg, frequency unknown has not been demonstrated.

Savella 12.5mg #60: Upheld

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

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

Decision rationale: The history and documentation do not objectively support the request for Savella 12.5 mg #60 at this time. The ODG state Savella is "under study as a treatment for

fibromyalgia syndrome. An FDA Phase III study demonstrated "significant therapeutic effects" of milnacipran for treatment of fibromyalgia syndrome. Milnacipran has been approved for the treatment of depression outside of the U.S. and is a dual serotonin- and norepinephrine-reuptake inhibitor (SNRI). (Rooks, 2007) Milnacipran, one of the pioneer serotonin and norepinephrine reuptake inhibitors (SNRIs), was designed from theoretic considerations to be more effective than selective serotonin reuptake inhibitors (SSRIs) and better tolerated than tricyclic antidepressants (TCAs). (Kasper, 2010). FDA has now approved milnacipran (Savella) for the management of fibromyalgia. Milnacipran should be prescribed with caution in patients with a history of seizure disorder, mania, or controlled narrow-angle glaucoma and should ordinarily not be prescribed in patients with substantial alcohol use or evidence of chronic liver disease. (FDA, 2009) As there is little to no evidence that the cause of fibromyalgia is related to industrial injuries, the use of Savella should be restricted to documented cases of fibromyalgia as part of an appropriate treatment plan.... In the US the FDA has approved milnacipran (Savella) for fibromyalgia, but not for depression."The specific indication for the use of Savella in this case is not clear described and none can be ascertained from the records. There is no evidence of a diagnosis of fibromyalgia and the ODG has not approved its use for depression. The claimant's pattern of use of this medication is unknown and the specific benefit to him of its use has not been clearly described. The claimant was also prescribed the antidepressant Trazodone and it is not clear why two antidepressants were recommended. Trials of other first line antidepressants have not been described. The medical necessity of the use of Savella 12.5 mg has not been demonstrated.

Fiorinal #120: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: PDR, 2014. Fiorinal

Decision rationale: The history and documentation do not objectively support the request for Fiorinal #120. The PDR recommend it for treatment of tension headaches. There is no evidence that this medication has been recommended for headaches. The indication for its use is not clearly stated in the records and none can be ascertained from the records. Specific measurable objective and functional benefit to him of the use of Fiorinal has not been described in the records. The medical necessity of the use of Fiorinal has not been clearly demonstrated.