

Case Number:	CM15-0189160		
Date Assigned:	10/01/2015	Date of Injury:	08/05/1998
Decision Date:	12/04/2015	UR Denial Date:	08/24/2015
Priority:	Standard	Application Received:	09/25/2015

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 51 year old female who sustained an industrial injury on 08-05-1998. Current diagnoses include generalized anxiety disorder and psychological factors affecting medical condition. Report dated 08-06-2015 noted that the injured worker presented for medication management for persistent symptoms of depression, anxiety, and stress related medical complaints. The prescribing physician noted that the medications all interact to improve anxiety, depression, confusion, emotional control and stress intensified medical complaints. Subjective findings included sleep difficulty, decreased energy, diminished self-esteem, excessive worry, restlessness, tension, inability to relax, suspicion, fear that people are following her, fear of being monitored, tension headaches, muscle tension, jaw clenching, peptic acid reaction, and constipation or diarrhea. Improvement in symptoms included comprehending TV, gets along better, less time in bed, goes out more, less yelling, and less panicky. Objective behaviors included a casual appearance. Previous treatments included medications, and therapies. The treatment plan included request for medications which included Vibryd, Brintillex, Seroquel, Zofran, Nuvigil, Maxalt, Cerefolin, and Prosom. The utilization review dated 08-24-2015, non-certified the request for Nuvigil, Maxalt, Cerefolin, and Prosom.

IMR ISSUES, DECISIONS AND RATIONALES

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

Nuvigil 150mg Qty 30 with 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain - Armodafinil (Nuvigil).

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)/Armodafinil (Nuvigil).

Decision rationale: The request is for the use of Armodafinil. The official disability guidelines state the following regarding this topic: Not recommended solely to counteract sedation effects of narcotics. Armodafinil is used to treat excessive sleepiness caused by narcolepsy or shift work sleep disorder. It is very similar to Modafinil. Studies have not demonstrated any difference in efficacy and safety between armodafinil and modafinil. (Tembe, 2011) For more information see also Modafinil (Provigil), where it is not recommended solely to counteract sedation effects of narcotics until after first considering reducing excessive narcotic prescribing, and it is noted that there should be heightened awareness for potential abuse of and dependence on this drug. Recently Cephalon produced a campaign advertising Nuvigil's ability to help shift workers stay alert on the job without impeding their ability to sleep during the day. The FDA is conducting an investigation into the possibility that this advertising or promotional information may have violated current regulations. (SEC, 2011) In this case, the use of this medication is not guideline supported. This is secondary to inadequate documentation of the condition narcolepsy or shift work sleep disorder, which are the indications listed. As such, the request is not medically necessary.

Maxalt 10 mg Qty 30 with 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines: Head - Triptans.

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

Decision rationale: The request is for the use of the medication Maxalt. The MTUS and ACOEM guidelines are silent regarding its use but the ODG guidelines state the following: Recommended for migraine sufferers. See Triptans. Rizatriptan (Maxalt) is a triptan drug developed by Merck & Co. for the treatment of migraine headaches. Meta-analyses of double-blind placebo-controlled studies have confirmed the superior efficacy of rizatriptan. (Gobel, 2010) While the Maxalt brand of rizatriptan therapy is more expensive than other triptans, savings can be expected in reduced migraine-related loss of work productivity compared with less effective treatments. (Mullins, 2007) (McCormack, 2005) According to the FDA Orange Book, equivalent generics have been approved for Maxalt, so generic rizatriptan would be recommended. (FDA, 2013) As stated above, the use of this medication for migraine headaches is guideline supported. In this case, there is inadequate documentation of history and

physical exam findings of migraine-type headaches found. In a progress notes, it is stated that an occipital nerve block is advised for headache relief suggesting a cervicogenic, cluster, or occipital neuralgia as the etiology. Pending receipt of further information, the request is not medically necessary.

Cerefolin Qty 30 with 2 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation URL [www.drugs.com/cdi/cerefolin-with-nae.html]; Official Disability Guidelines: Pain - Medical Foods; Mental Illness & Stress chapter.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain/B vitamins & vitamin B complex.

Decision rationale: The request is for a product which contains multivitamins. The ODG states the following regarding this topic: Not recommended for the treatment of chronic pain unless this is associated with documented vitamin deficiency. There are multiple B vitamins with specific symptoms due to deficiency: (1) vitamin B1 (thiamine) - beriberi; (2) vitamin B2 (riboflavin); (3) vitamin B3 (niacin or nicotinic acid) - pellegra; (4) vitamin B5 (pantothenic acid); (5) vitamin B6 (pyridoxine); (6) vitamin B7 (biotin); (7) vitamin B9 (folic acid) - megaloblastic anemia; (8) vitamin B12 (various cobalamins) - pernicious anemia, myelopathy, neuropathy, dementia, subacute combined degeneration of the spine, and decreased cognition. Treatment of vitamin B12 deficiency is generally parenteral. Vitamin B Complex contains the above 8 vitamins plus para-aminobenzoic acid, inositol, and choline. It is frequently used for treating peripheral neuropathy but its efficacy is not clear. A recent meta-analysis concluded that there are only limited data in randomized trials testing the efficacy of vitamin B for treating peripheral neuropathy (diabetic and alcoholic). Evidence was insufficient to determine whether specific B vitamins or B complex for these conditions was beneficial or harmful. (Ang-Cochrane, 2008) See B vitamins for depression in the Mental Health and Stress Chapter. In this case, the use of this product is not indicated. This is secondary to inadequate documentation of deficiency. As such, the request is not medically necessary.

Prosom 2 mg #30, with 2 refills: 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): Benzodiazepines.

Decision rationale: The request is for the use of a medication in the category of benzodiazepines. It is usually indicated to treat anxiety disorders but has been used short-term as a muscle relaxant. The MTUS guidelines state the following: 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 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, a medication in this class would not be advised for continued use due to the duration of therapy. As such, the request is not medically necessary. All benzodiazepine medications should be titrated down slowly to prevent an acute withdrawal syndrome.