MAXIMUS Federal Services

Case Number:	CM14-0052203		
Date Assigned:	07/07/2014	Date of Injury:	06/22/2009
Decision Date:	08/21/2014	UR Denial Date:	04/16/2014
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 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 applicant is a represented [redacted] employee who has filed a claim for major depressive disorder and chemical hypersensitivity reportedly associated with an industrial injury of June 22, 2009. In a Utilization Review Report dated April 16, 2014, the claims administrator denied a request for Nuvigil, Piracetam, Levoxyl, Pepcid, and vitamin D. In a psychiatric evaluation of October 25, 2013, the applicant was described as having primary diagnosis of adjustment disorder with mixed anxiety and depression with resultant Global Assessment of Functioning of 68. On October 28, 2013, the applicant was given a prescription for Nuvigil for shift-work disorder. It was stated that the applicant was working as a nurse and had an erratic schedule which was reportedly being normalized as a result of ongoing Nuvigil usage. The applicant was using Wellbutrin for antidepressant purposes, it was suggested. Piracetam was described as an over-the-counter medication for memory problems. The applicant was also given Levoxyl, Pepcid, and vitamin D. Cymbalta was discontinued owing to an adverse medication reaction. It was suggested that the applicant was maintaining work as a nurse. In a case manager note of November 26, 2013, the applicant's case manager stated that the applicant was demonstrating improvement with ongoing Nuvigil usage. On January 6, 2014, the applicant's psychiatrist stated that Nuvigil had improved her alertfullness during her work shift.

IMR ISSUES, DECISIONS AND RATIONALES

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

Nuvigil 150mg #30: Overturned

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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:nuvigil medication guide - Food and Drug Administrationwww.fda.gov/.../Drugs/.../UCM231717.p...--Food and Drug Administration.What is NUVIGIL? â¿¨NUVIGIL is a prescription medicine used to improve wakefulness in adults who are very sleepy due to one of the following diagnosed sleep disorders: -narcolepsy -obstructive sleep apnea (OSA). NUVIGIL is used with other medical treatments for this sleep disorder. NUVIGIL does not take the place of using your CPAP machine or other treatments that your doctor has prescribed for this condition. It is important that you continue to use these treatments as prescribed by your doctor. -shift work disorder (SWD).

Decision rationale: The California MTUS does not address the topic. However, the Food and Drug Administration (FDA) notes that Nuvigil is indicated in the treatment of narcolepsy, obstructive sleep apnea, and/or shift-work disorder. In this case, the attending provider has established that the applicant has developed shift-work disorder, reportedly imputed to her erratic working schedule as a nurse. Provision of Nuvigil to combat the same is indicated. Therefore, Nuvigil 150mg #30 is medically necessary.

Piracetam 800mg (unspecified quantity): Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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: ACOEM V.3 > Chronic Pain > General Principles of Treatment > Medications > Alternative TreatmentsRecommendation: Complementary or Alternative Treatments, Dietary Supplements, etc., for Chronic Pain Complementary and alternative treatments, or dietary supplements, etc., are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes.Strength of Evidence Not Recommended, Insufficient Evidence (I).

Decision rationale: The California MTUS does not address the topic of dietary supplements or alternative treatment such as Piracetam. However, the Third Edition ACOEM Guidelines note that dietary supplements, complementary treatments, and/or alternative treatments have no role in the treatment of chronic pain as they have not been shown to have any proven outcomes or meaningful benefits in the treatment of the same. In this case, no compelling applicant-specific information was proffered so as to offset the unfavorable ACOEM recommendation. Therefore, Piracetam 800mg is not medically necessary.

Levothyroxin 100mcg (unspecified quantity): Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 7-8. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence:Levoxyl (levothyroxine sodium) Tablet [King Pharmaceuticals, Inc.]Levoxyl (levothyroxine sodium) Tablet [King ... - Fdawww.accessdata.fda.gov/drugsatfda.../labe...--Food and Drug AdministrationINDICATIONS AND USAGELevothyroxine sodium is used for the following indications:Hypothyroidism -- As replacement or supplemental therapy in congenital or acquired hypothyroidism of any etiology, except transient hypothyroidism during the recovery phase of subacute thyroiditis. Specific indications include: primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) hypothyroidism and subclinical hypothyroidism. Primary hypothyroidism may result from functional deficiency, primary atrophy, partial or total congenital absence of the thyroid gland, or from the effects of surgery, radiation, or drugs, with or without the presence of goiter.Pituitary TSH Suppression -- In the treatment or prevention of various types of euthyroid goiters (see WARNINGS and PRECAUTIONS), including thyroid nodules (see WARNINGS and PRECAUTIONS), subacute or chronic lymphocytic thyroiditis (Hashimoto's thyroiditis), multinodular goiter (see WARNINGS and PRECAUTIONS) and, as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.

Decision rationale: While the California MTUS does not specifically address the topic of Levoxyl usage, pages 7 and 8 of the MTUS Chronic Medical Treatment Guidelines do stipulate that an attending provider using a drug for non-FDA labeled purposes has a responsibility to be well informed regarding usage of the same and should, furthermore, provide some compelling evidence to support such usage. The Food and Drug Administration (FDA) notes is that Levoxyl is indicated in the treatment of hypothyroidism and/or pituitary TSH suppression, such as in various types of goiter. In this case, however, it was not stated for what purpose Levoxyl was being employed. It did not appear that Levoxyl was being employed for hypothyroidism or pituitary TSH suppression purposes. No rationale for selection and/or ongoing usage of Levoxyl was proffered by the attending provider. Therefore, Levothyroxin 100mcg is not medically necessary.

Pepsid 40mg (unspecified quantity): Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI SYMPTOMS, AND CARDIOVASCULAR RISKS Page(s): 69.

Decision rationale: While page 69 of the California MTUS Chronic Medical Treatment Guidelines does support provision of H2 antagonist such as Pepcid to combat NSAID-induced dyspepsia, in this case, however, the progress notes provided do not establish the presence of any active symptoms of reflux, heartburn, and/or dyspepsia, either NSAID-induced or stand-alone, which would support provision of Pepcid. Therefore, Pepsid 40mg is not medically necessary.

Vitamin D 200IU (unspecified quantity): Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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: ACOEM V.3 > Chronic Pain > General Principles of Treatment > Medications > VitaminsVitaminsVitamins have been used to treat essentially all disorders. There has been particular interest in anti-oxidants; however, it should be noted that all anti-oxidants are simultaneously pro-oxidants,(520, 521) thus evidence of potential harm from the vitamins, particularly vitamin E, is also accumulating.(522-524) Evidence is poor that vitamins or minerals have beneficial therapeutic effects in normally over-nourished Western societies. However, there is evidence that vitamin C prevents the development of CRPS in patients with wrist fractures.(525, 526) (The patient population studied was mostly elderly females which may limit the generalizability of these results, which also have not been confirmed in occupational populations.)Recommendation: Vitamins for Chronic Pain Vitamins are not recommended for treatment of chronic pain if documented deficiencies or other nutritional deficit states are absent.Strength of Evidence Not Recommended, Insufficient Evidence (I).

Decision rationale: The California MTUS does not address the topic. As noted in the Third Edition ACOEM Guidelines, vitamins are not recommended in the absence of documented nutritional deficit states or nutritional deficiencies. In this case, there is no evidence that the applicant has a bona fide vitamin D deficiency. Therefore, Vitamin D 200IU request is not medically necessary.