MAXIMUS Federal Services

Case Number:	CM14-0002600		
Date Assigned:	01/24/2014	Date of Injury:	02/02/2009
Decision Date:	06/19/2014	UR Denial Date:	12/30/2013
Priority:	Standard	Application Received:	01/07/2014

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 patient is an employee of [redacted] and has submitted a claim for cervicalgia, left rotator cuff syndrome, thoracic outlet syndrome, lumbar pain, Gastroesophageal Reflux Disease (GERD), irritable bowel syndrome, hemorrhoids, sleep disorder secondary to stress, rule out obstructive sleep apnea, eczema, and pericarditis secondary to lupus associated with an industrial injury date of 02/02/2009. Treatment to date has included chemodenervation with botulinum toxin, myofascial trigger point injections, psychotherapy, home exercises, and medications such as Flexeril, Prozac, Xanax, Prilosec, Cosamin, Plaquenil, Gaviscon, Vitamin D3, Advair diskus, Restoril, Dexillant, and Sentra. Medical records from 2009 to 2014 were reviewed showing that patient complained of persistent, moderate to severe pain at the neck, left shoulder, upper and lower back. It was described as dull, aching, sharp, and stabbing with associated stiffness, tightness, muscle spasm, and knots. She likewise complained of tension headaches. The neck pain radiated to bilateral upper extremities with noted weakness at the left, while back pain radiated to left lower extremity up to the toes with associated numbness and tingling sensation. Aggravating factors included side-to-side movement, bending, leaning, lifting, carrying, prolonged sitting greater than 30 minutes, climbing stairs and walking. This resulted to difficulties in doing self-care, personal hygiene, hand activities, and other physical activities. Patient likewise complained of severe impairment with respect to sleep, as she can only sleep less than four hours a night due to pain. She experienced constipation, diarrhea, and chest pain with worsening acid reflux. Patient is obese. Physical examination revealed limitation of motion of the cervical spine, left shoulder joint, thoracic spine, and lumbar spine on all planes. Deep tendon reflexes were equal and symmetric. Motor testing was normal for all extremities, except for left deltoids, graded 4/5. Sensation was intact. There was tenderness over the periumbilical region without abdominal distension. Objective findings for

the pulmonary and cardiovascular systems were unremarkable. There were no joint deformities or swelling. Utilization review from 12/30/2013 denied the requests for Gaviscon three times a day due to lack of documentation on the dosage and quantity; Probiotics because there was no documented indication; Advair Diskus 250/50mg because there is no available information for its necessity; Vitamin D3 650,000 weekly due to lack of documented proof of nutritional deficiencies; sunscreen SPF 50 due to lack of medical necessity; Restoril due to lack of benefits from previous use; Dexillant due to lack of documentation regarding gastric distress; Sentra PM due to lack of evidence on efficacy; urine drug screen because there was no noted aberrant drug behavior necessitating screening; sleep study with cardiorespiratory testing because there are no documented sleep apnea symptoms; and labs because of unspecified tests.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gaviscon 3 Times a day, #1 bottle: 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: Food And Drug Administration, Gaviscon (http://www.fda.gov/drugs/developmentapprovalprocess/ucm079068.htm).

Decision rationale: The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, the Food and Drug Administration was used instead. It states that Gaviscon's activity in treating reflux acidity is made possible by the physical-chemical properties of the inactive ingredients, sodium bicarbonate and alginic acid. In this case, patient has been persistently complaining of heartburn, regurgitation, and chest pain. On 10/04/2013, patient underwent esophageal pH monitoring test, which revealed significant acid reflux corroborating her symptoms. Therefore, the request for Gaviscon 3 times a day, #1 bottle is medically necessary.

Probiotics, #60: 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: National Institutes of Health, National Center for Complementary and Alternative Medicine (http://nccam.nih.gov/health/probiotics/introduction.htm).

Decision rationale: CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of

Workers Compensation, the National Institutes of Health Guideline was used instead. It states that Probiotics are live microorganisms (e.g., bacteria) that are either the same as or similar to microorganisms found naturally in the human body and may be beneficial. The U.S. Food and Drug Administration (FDA) has not approved any health claims for Probiotics. In this case, patient has had episodes of alternating constipation and diarrhea, hence, a diagnosis of irritable bowel syndrome. However, medical records submitted and reviewed do not provide a documented indication for Probiotics as the FDA has not approved health claims for Probiotics. The medical necessity has not been established. Therefore, the request for Probiotics, #60 is not medically necessary.

Advair Diskus 250/50mg, #1: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines ODG - Pulmonary (Acute & Chronic) Updated 10/29/13.

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: Food and Drug Administration, Advair Diskus (http://www.fda.gov/safety/medwatch/safetyinformation/safety-relateddruglabelingchanges/ucm117699.htm) and http://www.drugs.com/pro/advair.html.

Decision rationale: The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, the Food and Drug Administration Guideline was used instead. It states that Advair Diskus contains fluticasone propionate and salmeterol; only used for patients not adequately controlled on a long-term asthma control medication. Once asthma control is achieved and maintained, assess the patient at regular intervals for possible step-down therapy. In this case, patient was noted to have small airway disease and was prescribed with Advair since 2012 on a twice-daily basis. However, recent progress reports do not provide evidence that patient has episodes of difficulty breathing. This is further corroborated by normal physical examination findings of the pulmonary system. It is unclear if a step-down therapy was initiated, and eventually failed, which may necessitate continuation of this medication. The medical necessity has not been established. Therefore, the request for Advair Diskus 250/50mg, #1 is not medically necessary.

Vitamin D3 650,000 Units Weekly, #1 IS: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MTUS: ACOEM Guidelines-Evaluation & Management (E&M).

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: Evaluation, Treatment, and Prevention of Vitamin D Deficiency: An Endocrine

Society Clinical Practice Guideline 2011 (https://www.endocrine.org/education-and.../clinical-practice-guidelines).

Decision rationale: The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, the Endocrine Society Clinical Practice Guideline 2011 was used instead. It states that homebound individuals with limited mobility, patients who have intestinal malabsorption, those who are receiving long-term anti-convulsant or glucocorticoid therapy, patients who suffer from chronic granuloma disorders, obese, among others, are particularly at risk for vitamin D deficiency. The recommendation is to treat adults who are vitamin D deficient with 50,000 IU of vitamin D2 or D3 once a week. The patient has a diagnosed case of vitamin D deficiency and has started supplementation since 2012. She likewise has tuberculosis, obesity, irritable bowel syndrome; and she is on long-term benzodiazepine (Restoril). Given the above patient characteristics, the medical necessity for supplementation has been established. Therefore, the request for Vitamin D3, #6 50,000 units weekly is medically necessary.

Sunscreen SPF 50, #1: 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: American College of Rheumatology, Systemic Lupus Erythematosus.

Decision rationale: The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, the American College of Rheumatology Clinical Practice Guideline was used instead. It states that the best way to control lupus is to avoid sun exposure. Sunlight can cause a lupus rash to flare and may even trigger a serious flare of the disease itself. When outdoors on a sunny day, wear protective clothing and use lots of sunscreen. Patient has a diagnosed case of systemic lupus erythematosus and has been prescribed to use sunscreen to limit episodes of flare. The medical necessity has been established. Therefore, the request for Sunscreen SPF 50, #1 is medically necessary.

Restoril: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines MTUS: CHRONIC PAIN MEDICAL TREATMENT GUIDELINES, BENZODIAZEPINES, page 23.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24. Decision based on Non-MTUS Citation page 24.

Decision rationale: As stated on page 64 of CA MTUS Chronic Pain Medical Treatment Guidelines, benzodiazepines range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. They 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. In this case, patient has a diagnosed case of insomnia secondary to chronic pain, and anxiety. Physical examination findings also include presence of muscle spasm. However, temazepam (Restoril) has been prescribed since 2012. There is no discussion concerning its indication despite exceeding the guideline recommendation. There is a risk of dependence; hence, benefits should outweigh the risk. There should be a documented rationale in this regard. Furthermore, the present request failed to specify the dosage, frequency, and amount of drug to be dispensed. Therefore, the request for Restoril is not medically necessary.

Dexillant (Refill): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Non-Steroidal Anti-Inflammatory Drugs (NSAID), Gastrointestinal (GI) Symptoms & Cardiovascular Risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines MTUS: CHRONIC PAIN MEDICAL TREATMENT GUIDELINES, 68.

Decision rationale: Page 68 of the CA MTUS Chronic Pain Medical Treatment Guidelines and the FDA support proton pump inhibitors in the treatment of patients with Gastrointestinal (GI) disorders such as gastric/duodenal ulcers, Gastroesophageal Reflux Disease (GERD) , erosive esophagitis, or patients utilizing chronic Non-Steroidal Anti-Inflammatory Drugs (NSAID) therapy. In this case, patient has been persistently complaining of heartburn, regurgitation, and chest pain. On 10/04/2013, patient underwent esophageal pH monitoring test, which revealed significant acid reflux corroborating her symptoms. She was previously on Prilosec, however, patient reported no relief of symptoms; hence, she was shifted into Dexlansoprazole (Dexilant). The medical necessity has been established, however, the present request failed to specify the dosage, frequency, and amount of drug to be dispensed. Therefore, the request for Dexillant (refill) is not medically necessary.

Sentra PM #1 bottle: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines ODG- Medical Foods and Combinations.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG) PAIN CHAPTER.

Decision rationale: The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, the Official Disability Guidelines (ODG), Pain Chapter was used instead. It states that Sentra PM is a medical food intended for use in management of sleep disorders associated with depression, which is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with

choline deficiency secondary to liver deficiency. Glutamic Acid is used for treatment of hypochlohydria and achlorhydria including those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. 5-hydroxytryptophan has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity, and sleep disorders. In this case, the patient has a diagnosed case of anxiety, obesity, and sleep disorder; however the present request for Sentra PM failed to indicate the frequency of intake. Therefore, Sentra PM #1 bottle is not medically necessary.

Urine Drug Screen, #1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines Page(s): 43.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines Page(s): 68.

Decision rationale: Page 78 of CA MTUS Chronic Pain Medical Treatment Guidelines states that a urine analysis is recommended as an option to assess for the use or the presence of illegal drugs, to assess for abuse, to assess before a therapeutic trial of opioids, addiction, or poor pain control in patients under on-going opioid treatment. In this case, the patient's current medications include Flexeril, Prozac, Xanax, Cosamin, Plaquenil, Gaviscon, Vitamin D3, Advair diskus, Restoril, Dexillant, and Sentra. The patient is not on opioid and there are no plans for starting one. Urine drug screen, dated 11/19/2013, revealed positive levels for norfluoxetine, while a repeat testing on 12/19/2013 showed no detectable levels. It is important to note that Selective Serotonin Reuptake Inhibitors (SSRIs) were not included in the list of tested drugs on the latter test. There is likewise no report regarding presence of aberrant drug behaviors in the patient, which may necessitate frequent urine drug monitoring. Therefore, the request for urine drug screen, #1 is not medically necessary.

Sleep Study With Cardiorespiratory Testing, #1: Upheld

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

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

Decision rationale: The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, the Official Disability Guidelines (ODG), Pain Chapter was used instead. It states that Polysomnography is recommended after at least six months of an insomnia complaint (at least four nights a week), unresponsive to behavior intervention and sedative/sleep-promoting medications, and after psychiatric etiology has been excluded. In this case, the patient has been complaining of difficulty in sleeping since 2012 without response to oral therapy. A

progress report, dated 11/09/2013, cited that a sleep study was already executed at the patient's home to rule out obstructive sleep apnea. However, the official result is not available for review. There is no documented indication for a repeat sleep study in this case. Therefore, the request for sleep study with cardiorespiratory testing, #1 is not medically necessary.

Labs: 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: Comprehensive Metabolic Panel. Medlineplus. (http://www.nlm.nih.gov/medlineplus/ency/article/003468.htm).

Decision rationale: CA MTUS does not specifically address comprehensive metabolic panels. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, MedlinePlus, a web site of the National Institutes of Health produced by the National Library of Medicine, was used instead. According to MedlinePlus, a comprehensive metabolic panel is a group of blood tests that provide an overall picture of the body's chemical balance and metabolism. In this case, laboratory results, dated 12/19/2013, revealed normal C3 and C4 complement levels, Blood Urea Nitrogen (BUN), creatinine, liver function test, however with elevated SED. These tests are necessary for monitoring of patient's lupus, as well as, possible adverse effects from multiple drug usage. However, the present request failed to identify the specific laboratory tests being requested. Therefore, the request for labs is not medically necessary.