

Case Number:	CM15-0125938		
Date Assigned:	07/10/2015	Date of Injury:	06/02/2003
Decision Date:	09/04/2015	UR Denial Date:	06/01/2015
Priority:	Standard	Application Received:	06/30/2015

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: New York

Certification(s)/Specialty: Pediatrics, Internal 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 49 year old male, who sustained an industrial injury on 6/2/2003. The current diagnoses are abdominal pain, gastropathy, secondary to NSAIDs, acid reflux, irritable bowel syndrome, aggravated by medication, hiatal hernia, obesity, post-traumatic weight gain (over 60 pounds), and erectile dysfunction. According to the progress report dated 5/13/2015, the injured worker complains of worsening abdominal pain and acid reflux. In addition, he notes diarrhea and constipation (varies). The physical examination reveals his abdomen to be soft with normoactive bowel sounds. The current medications are Dexilant, Citrucel, Miralax, Colace, Probiotics, Viagra, Androgel, Amitiza, Glipizide, Metformin, Simvastatin, Lisinopril, Amlodipine, Norco, and OxyContin. There is documentation of ongoing treatment with Viagra, Androgel, Dexilant, and Probiotics since at least 3/4/2015. Although, the records indicated a free testosterone level was ordered, there were no results available for review. Treatment to date has included medication management. As of 3/24/2015 the injured worker was considered permanent and stationary. A request for Viagra, Androgel, Dexilant, and Probiotics has been submitted.

IMR ISSUES, DECISIONS AND RATIONALES

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

Viagra 25mg #15: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Literature published by the drug manufacture, Pfizer (August 2003).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Testosterone replacement for hypogonadism (related to opioids) Page(s): 110-111. Decision based on Non-MTUS Citation uptodate.com - sildenafil.

Decision rationale: The CA MTUS and Official Disability Guidelines are silent regarding the use of Viagra. According to MTUS guidelines the etiology of decreased sexual function, a symptom of hypogonadism, is confounded by several factors including the following: (1) The role of chronic pain itself on sexual function; (2) The natural occurrence of decreased testosterone that occurs with aging; (3) The documented side effect of decreased sexual function that is common with other medications used to treat pain (SSRIs, tricyclic antidepressants, and certain anti-epilepsy drugs); & (4) The role of comorbid conditions such as diabetes, hypertension, and vascular disease in erectile dysfunction. There is no documentation that testosterone level was low or that the erectile dysfunction was temporally related to initiation of medications for treatment of pain which could indicate a side effect. Viagra is indicated for idiopathic erectile dysfunction and pulmonary arterial hypertension. This request is not medically necessary and appropriate.

AndroGel 30g #1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Testosterone replacement for hypogonadism (related to opioids).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Testosterone replacement for hypogonadism (related to opioids) Page(s): 110-111.

Decision rationale: According to the CA MTUS Chronic Pain Medical Treatment Guidelines, testosterone replacement is recommended in limited circumstances for patients taking high-dose long-term opioids with documented low testosterone levels. Hypogonadism has been noted in patients receiving intrathecal opioids and long-term high dose opioids. Routine testing of testosterone levels in men taking opioids is not recommended; however, an endocrine evaluation and/or testosterone levels should be considered in men who are taking long term, high dose oral opioids or intrathecal opioids. If needed, testosterone replacement should be done by a physician with special knowledge in this field. In this case, the submitted medical records failed to provide documentation how low testosterone levels would be related to the injured workers industrial injury. In addition, although, the records indicated a free testosterone level was ordered, there were no results available for review to support ongoing supplementation. Therefore, based on CA MTUS and submitted medical records, the request for AndroGel is not medically necessary.

Dexilant #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Testosterone replacement for hypogonadism (related to opioids).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines GI symptoms & cardiovascular risk Page(s): 68-69.

Decision rationale: The CA MTUS Chronic Pain Medical Treatment Guidelines recommend proton pump inhibitors be used with precautions. The clinicians should weigh the indications for NSAIDs against gastrointestinal risk factors. Factors determining if a patient is at risk for gastrointestinal events include: age greater than 65 years, history of peptic ulcer, GI (gastrointestinal) bleeding, or perforation, concurrent use of aspirin, corticosteroids, and/or anticoagulant or high dose/multiple NSAID use. The guidelines indicate that patients with no risk or cardiovascular disease: Non-selective NSAIDs OK (e.g, ibuprofen, naproxen, etc). Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 ug four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardio protection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxyn plus low-dose aspirin plus a PPI. In this case, the submitted medical records failed to provide documentation that the injured worker is currently being treated with NSAIDs. In addition, although, there is documentation of gastrointestinal upset, there is no documentation that the injured worker is at risk for gastrointestinal events or cardiovascular complications to support the use of proton-pump inhibitors. Therefore, based on CA MTUS guidelines and submitted medical records, the request for Dexilant is not medically necessary.

Probiotics #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.drugs.com.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation uptodate.com - Probiotics for gastrointestinal diseases.

Decision rationale: The CA MTUS and Official Disability Guidelines are silent regarding the use of Probiotics. Several probiotic preparations have promise in preventing or treating various conditions. However, most studies have been small, and many have important methodologic limitations, making it difficult to make unequivocal conclusions regarding efficacy, especially when compared with proven therapies. There are no preparations that are FDA approved and most are not reimbursed by insurers. Enthusiasm for probiotics has outpaced the scientific evidence. Large, well-designed multicenter controlled clinical trials are needed to clarify the role of specific probiotics in different well-defined patient populations. This request is not medically necessary.