

Case Number:	CM14-0094031		
Date Assigned:	07/25/2014	Date of Injury:	12/11/2001
Decision Date:	10/07/2014	UR Denial Date:	05/22/2014
Priority:	Standard	Application Received:	06/20/2014

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 a 45-year-old female who has submitted a claim for constipation associated with an industrial injury date of December 11, 2001. Medical records from 2013 to 2014 were reviewed. The patient was being treated for chronic pain and has been utilizing opioids as far back as April 2013. At present, the patient complains of constipation and worsening of acid reflux. Physical examination showed morbid obesity and +1 epigastric pain and tenderness. There is positive hiatal hernia noted. The diagnoses include gastroesophageal reflux disease secondary to NSAIDs; irritable bowel syndrome, constipation type; chronic gastritis per EGD; hiatal hernia per EGD; Barrett's esophagitis per EGD; and morbid obesity. Treatment to date has included tramadol, Norco, tizanidine, diclofenac, Prilosec, Dexilant, Gaviscon, probiotics, and Metamucil powder. Utilization review from May 22, 2014 denied the request for Gaviscon 1 bottle, 1 Tbsp 3x daily (2 refills), probiotics #60 2x daily (2 refills), Metamucil powder 1 bottle used as directed (2 refills), and Dexilant 60mg daily (2 refills). There is insufficient information provided to establish medical necessity.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gaviscon 1 bottle, 1 tbsp 3xdaily (2refills): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 68-69.

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, Gaviscon intake was noted as far back as December 2013. However, there was no evidence that this has helped relieve gastrointestinal symptoms. Furthermore, current intake of Dexilant was noted. There was no objective evidence that Dexilant has failed to relieve acid reflux that warrant additional medication. The medical necessity of Gaviscon was not established due to lack of information. There was no compelling indication for its continued use at this time. Therefore, the request for Gaviscon 1 bottle, 1 tbsp 3xdaily (2refills) is not medically necessary.

Probiotics #60 2 x daily (2 refills): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.ncbi.nlm.nih.gov/pubmed/12369194>

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: 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 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 to health. The U.S. Food and Drug Administration (FDA) has not approved any health claims for probiotics. In this case, probiotic intake was noted as far back as December 2013. However, there was no objective evidence that this has helped to improve gastrointestinal symptoms. Furthermore, there is little support for the use of probiotics by the FDA. The medical necessity has not been established. There was no compelling rationale for continued use of this medication. Therefore, the request for Probiotics #60 2 x daily (2 refills) is not medically necessary.

Metamucil powder 1 bottle use as directed (2 refills): Upheld

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

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, Metamucil (<http://www.fda.gov/OHRMS/dockets/dailys/03/Aug03/081503/78n-00361-bkg0004-04-tab6-vol1.pdf>); Aetna, Psyllium (<http://aetna-health.healthline.com/smartsources/healthwisecontent/Multum/d01018a1#d01018a1-important>)

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, Metamucil was used instead. Psyllium (Metamucil) is a bulk forming laxative. Aetna states that laxatives may be habit-forming if they are used too often or for too long. In this case, the patient was diagnosed with irritable bowel syndrome, constipation type for which Metamucil was prescribed dating as far back as December 2013. However, there was no evidence that this medication has helped relieve constipation. Moreover, the documents provided did not mention the dosing and frequency of use of Metamucil. The guideline states that laxatives may be habit-forming if they are used too often or for too long. The medical necessity cannot be established at this time due to insufficient information. Therefore, the request for Metamucil powder 1 bottle use as directed (2 refills) is not medically necessary.

Dexilant #30, 60mg daily (2 refills): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 68-69.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Proton pump inhibitors (PPI)

Decision rationale: According to page 68 of CA MTUS Chronic Pain Medical Treatment Guidelines, proton pump inhibitors are used in patients on NSAID therapy who are at risk for GI events. Risk factors includes age > 65; history of peptic ulcer, GI bleed, or perforation; concurrent use of ASA, corticosteroids, or anticoagulant; and high dose or multiple NSAID use. According to ODG, omeprazole OTC tablets or lansoprazole 24HR OTC are recommended for an equivalent clinical efficacy and significant cost savings. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses including dexlansoprazole (Dexilant). In this case, the patient has been taking Dexilant since at least December 2013. Prior Prilosec use was also noted dating as far back as April 2013. However, there was no evidence that Dexilant has helped relieve the patient's gastrointestinal symptoms better than Prilosec. The guideline states that omeprazole and dexlansoprazole have demonstrated equivalent clinical efficacy and safety at comparable doses. The medical necessity has not been established. There was no compelling rationale to recommend Dexilant over Prilosec. Therefore the request for Dexilant #30, 60mg daily (2 refills) is not medically necessary.