MAXIMUS Federal Services

Case Number:	CM14-0191434		
Date Assigned:	12/19/2014	Date of Injury:	09/24/2009
Decision Date:	01/16/2015	UR Denial Date:	10/27/2014
Priority:	Standard	Application Received:	11/17/2014

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 Physical Medicine and Rehabilitation, has a subspecialty in Pain Management 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 60 year old male with an injury date of 09/24/09. Based on the 07/31/14 progress report provided by treating physician, the patient complains of chronic neck, shoulders, arms, lower back and left rib pain with numbness and tingling sensation from shoulders down to the hands. Patient also complains of heartburn and indigestion. Patient has history of broken rib and injury to shoulder as result of injury. Patient is status post right shoulder surgery September 2010 and left shoulder January 2012. Patient's medications included Sentra AM, Sentra PM, Gaviscon, MiAcid and Floranex per provider report dated 07/31/14. Per progress report dated 09/17/14, patient complains of unchanged acid reflux, bloating, irritable bowel syndrome and difficulty sleeping. Patient's medications included Dexilant, Simethione, Amitiza, Gaviscon, Sentra AM and Sentra PM per progress report dated 09/17/14. Patient has been totally disabled since 09/24/09 and remains permanent and stationary. Diagnosis since 2012 by internist, per progress report dated 07/31/14- gastroesophageal reflux disease- gastritis- indigestion.Diagnosis 07/31/14- abdominal pain- irritable bowel syndrome- sleep disorder, rule out obstructive sleep apnea- gastritis- internal hemorrhoids- external hemorroids- gastric intestinal metaplasia.The utilization review determination being challenged is dated 10/27/14. The rationale follows:1) Dexilant: "...based on lack of improvement of symptoms with use, continuation is not appropriate."2) Simethicone: "no evidence to support the use of activated charcoal containing products, 'antiflatulents,' simethicone, and other agents in IBS."3) Amitiza: "...the patient appears to be taking this medication in the management of irritable bowel syndrome... Based on the lack of benefit, continuation is not appropriate." Treatment reports were provided from 04/30/14 - 12/12/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

1 prescription of Dexilant 30mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms And Cardiovascular Risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms And Cardiovascular Risk. Page(s): 69. Decision based on Non-MTUS Citation http://www.drugs.com/pro/dexilant.html

Decision rationale: The patient presents with chronic neck, shoulders, arms, lower back and left rib pain with numbness and tingling sensation from shoulders down to the hands. Patient has history of broken rib and injury to shoulder as result of injury. Patient is status post right shoulder surgery September 2010 and left shoulder January 2012. The request is for 1 prescription of Dexilant 30MG #30 (1x daily). Patient also complains of heartburn and indigestion. Patient has been diagnosed with gastroesophageal reflux disease, gastritis and indigestion since 2012. Patient's medications included Dexilant, Simethione, Amitiza, Gaviscon, Sentra AM and Sentra PM per progress report dated 09/17/14. Patient has been totally disabled since 09/24/09 and remains permanent and stationary. FDA labeled indications for Dexilant: "for Healing of Erosive Esophagitis. Dexilant is indicated for healing of all grades of erosive esophagitis (EE) for up to eight weeks. Dexilant is also indicated to maintain healing of EE and relief of heartburn for up to six months. Dexilant is indicated for the treatment of heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD) for four weeks." Regarding NSAIDs and GI/CV risk factors, MTUS requires determination of risk for GI events including age >65; history of peptic ulcer, GI bleeding or perforation; concurrent use of ASA, corticosteroids, and/or an anticoagulant; or high dose/multiple NSAID. MTUS pg 69 states "NSAIDs, GI symptoms and cardiovascular risk, Treatment of dyspepsia secondary to NSAID therapy: Stop the NSAID, switch to a different NSAID, or consider H2-receptor antagonists or a PPI." Provider has not provided reason for the request. Patient's diagnosis on 07/31/14 included abdominal pain, irritable bowel syndrome and gastric intestinal metaplasia. Per progress report dated 09/17/14, patient complains of unchanged acid reflux, bloating, irritable bowel syndrome and difficulty sleeping. Review of medical records do not indicate the patient was currently taking any NSAIDs to warrant a prophylactic use of the PPI, according to guidelines. Furthemore, there is no diagnosis of erosive esophagitis or GERD, and provider has not documented how the requested medication is helping patient manage his symptoms. Therefore, the request is not medically appropriate.

1 prescription of Simethicone 80mg #60: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation World Gastroenterology Organisation (WGO) World Gastroenterology Organisation Global Guideline: Irritable Bowel Syndrome: a global perspective. Munich (Germany): World Gastroenterology Organisation (WGO); 2009 Apr 20. 20 p.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Drugs.com , Simethiocone

Decision rationale: The patient presents with chronic neck, shoulders, arms, lower back and left rib pain with numbness and tingling sensation from shoulders down to the hands. Patient has history of broken rib and injury to shoulder as result of injury. Patient is status post right shoulder surgery September 2010 and left shoulder January 2012. The request is for 1 prescription of Simethione 80MG #60 (2 xs daily). Patient also complains of heartburn and indigestion. Patient has been diagnosed with gastroesophageal reflux disease, gastritis and indigestion since 2012. Patient's medications included Dexilant, Simethione, Amitiza, Gaviscon, Sentra AM and Sentra PM per progress report dated 09/17/14. Patient has been totally disabled since 09/24/09 and remains permanent and stationary. Simethione is an anti-flatulent. It works by breaking up gas bubbles, which makes gas easier to eliminate. Drugs.com states indication for use is "Relief of painful symptoms and pressure of excess gas in digestive tract; adjunct in treatment of many conditions in which gas retention may be problem, such as postoperative gaseous distention and pain, endoscopic examination, air swallowing, functional dyspepsia, peptic ulcer, spastic or irritable colon, diverticulosis." Provider has not provided reason for the request. Patient's diagnosis on 07/31/14 included abdominal pain, irritable bowel syndrome and gastric intestinal metaplasia. Per progress report dated 09/17/14, patient complains of unchanged acid reflux, bloating, irritable bowel syndrome and difficulty sleeping. UR letter dated 10/27/14 states "no evidence to support the use of activated charcoal containing products, 'antiflatulents,' simethicone, and other agents in IBS." However, Drugs.com supports Simethiocone for irritable colon, for which patient has been diagnosed with. The request appears reasonable, therefore it is medically necessary.

1 prescription of Amitiza 8mcg #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Prophylactic Medication Page(s): 76 to 78. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Lubiprostone Amitiza

Decision rationale: The patient presents with chronic neck, shoulders, arms, lower back and left rib pain with numbness and tingling sensation from shoulders down to the hands. Patient has history of broken rib and injury to shoulder as result of injury. Patient is status post right shoulder surgery September 2010 and left shoulder January 2012. The request is for 1 prescription of Amitiza 8mg #60 (BID). Patient also complains of heartburn and indigestion. Patient has been diagnosed with gastroesophageal reflux disease, gastritis and indigestion since 2012. Patient's diagnosis on 07/31/14 included abdominal pain, irritable bowel syndrome and gastric intestinal metaplasia. Patient's medications included Dexilant, Simethione, Amitiza, Gaviscon, Sentra AM and Sentra PM per progress report dated 09/17/14. Patient has been totally disabled since 09/24/09 and remains permanent and stationary.ODG-TWC, Pain Chapter, Lubiprostone (Amitiza) Section states: "Recommended only as a possible second-line treatment for opioid-induced constipation. See Opioid-induced constipation treatment." MTUS pages 76 to

78 discuss prophylactic medication for constipation when opiates are used. Provider has not provided reason for the request. It appears Amitiza was prescribed to treat patient's IBS; however provider has not discussed how the medication is helping the patient. Per progress report dated 09/17/14, patient complains of unchanged acid reflux, bloating, irritable bowel syndrome and difficulty sleeping. Review of medical records do not indicate the patient was on opiod therapy to warrant prophylactic constipation treatment. Furthermore, guidelines recommend Amitiza only as a possible second-line treatment for opioid-induced constipation. The request is not inline with guideline recommendations; therefore it is not medically necessary.