MAXIMUS Federal Services

Case Number:	CM15-0178678		
Date Assigned:	09/28/2015	Date of Injury:	07/24/2012
Decision Date:	11/30/2015	UR Denial Date:	08/06/2015
Priority:	Standard	Application Received:	09/10/2015

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: California, Arizona
Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 30-year-old female, with a reported date of injury of 07-29-2012. The diagnoses include abdominal pain, mild acute gastritis, acid reflux, constipation, internal hemorrhoids, bright red blood from the rectum, and gastric distress. Treatments and evaluation to date have included occupational therapy, Nexium, Gaviscon, Citrucel, Simethicone (since at least 03-2015), Probiotics (since at least 03-2015), Amitiza, Sentra AM (since at least 03-2015), Sentra PM (since at least 03-2015), Naproxen, Tylenol #3, Tramadol, Motrin, and Omeprazole. The diagnostic studies to date have included a urine drug screen on 08-18-2015 with negative findings. The progress report dated 06-16-2015 indicates that the injured worker reported unchanged abdominal pain, improved acid reflux, constipation, and episodes of blood in the stool. The physical examination showed a soft abdomen, and normoactive bowel sounds. The injured worker's disability status was deferred to the primary treating physician. The request for authorization was dated 06/16/2015. The treating physician requested Probiotics #60, Sentra AM #60, three bottles, Sentra PM #60 with three bottles, Simethicone 80mg #60, Nexium 40mg #30, Lab: CMP (complete metabolic panel), Lab: CBC (complete blood count), Lab: Amylase, Lab: Lipase, and body composition study done on 06-16-2015.Outpatient surgical center note 8/18/2015 was reviewed, that described a July 2014 upper endoscopy with findings of mild gastritis. Due to persistent symptoms, another repeat endoscopy was authorized and performed 8/18/2015. The results were completely normal. On 08-04-2015, Utilization Review (UR) non-certified the request for Probiotics #60, Sentra AM #60, three bottles, Sentra PM #60 with three bottles, Simethicone 80mg #60, Nexium 40mg #30, Lab: CMP (complete metabolic panel), Lab: CBC (complete blood count). Lab: Amylase, lab: Lipase, and body composition study done on 06-16-2015.

IMR ISSUES, DECISIONS AND RATIONALES

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

Probiotics #60: Overturned

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Library of Medicine.

Decision rationale: A search of the National Library of Medicine and other online resources reveals that proven benefits of probiotics include the treatment of acute and anti-biotic associated diarrhea; applications with substantial evidence include the prevention of atopic eczema and traveler's diarrhea; promising applications include the prevention of respiratory infections in children, prevention of dental caries, elimination of nasal pathogen carriage, prevention of relapsing Clostridium Difficile-induced gastroenteritis, and treatment of inflammatory bowel disease; and proposed future applications include the treatment of rheumatoid arthritis, treatment of irritable bowel syndrome, cancer prevention, prevention of ethanol-induced liver disease, treatment of diabetes, and prevention or treatment of graft-versus-host disease. The use of probiotics in medical practice is rapidly increasing, as are studies that demonstrate the efficacy of probiotics. The injured worker carries a diagnosis of irritable bowel syndrome and maintenance of gut flora with the use of Probiotics is reasonable. As such, this request is medically necessary.

Sentra AM #60 3 bottles: 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), Pain Chapter, Medical foods.

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

Decision rationale: Medical food is defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as a food which is formulated to be consumed or administered entirely under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Medical foods do not have to be registered with the FDA and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. As it pertains to Sentra AM, "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." Additionally, "Glutamic Acid is used for treatment of hypochlorhydria and achlorhydria. Treatment

indications include those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. It is generally used for digestive disorders in complementary medicine." Evidence based guidelines do not support the use of medical food for the cited injuries or conditions and as such, this request is not medically necessary.

Sentra PM #60 3 bottles: 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), Pain Chapter, Medical foods.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental illness and Stress / Sentra PM.

Decision rationale: According to the ODG, Sentra PM is a medical food used to treat insomnia, consisting of a proprietary blend of choline and 5-HTP. It is not recommended until independent unbiased studies are published. Evidence based guidelines do not support the use of medical foods for the cited injuries. This request is not medically necessary.

Simethicone 80mg #60: Overturned

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

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

Decision rationale: The FDA states that Simethicone is indicated for relief of painful symptoms of pressure due to excess gas in the digestive tract; adjunct in treatment of many conditions in which gas retention may be a problem, such as post-operative gaseous distention and pain, endoscopic examination, air swallowing, functional dyspepsia, peptic ulcer, spastic or irritable colon, diverticulosis (http://www.drugs.com/ppa/simethicone.html). This injured has chronic abdominal pain complaints, and irritable bowel syndrome. This request as such, is reasonable and will be medically necessary.

Nexium 40mg #30: 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), Pain Chapter, proton pump inhibitors.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: According to the MTUS Chronic Pain Guidelines, Proton Pump Inhibitors are used to treat symptoms of gastritis, peptic ulceration, acid reflux, and/or dyspepsia related to non-steroidal anti-inflammatories (NSAIDs). Those on NSAIDs at high risk for GI events should be considered for antacid therapy. Factors determining if a patient is at risk for gastrointestinal events include age greater than 65 years, history of peptic ulcer, GI bleeding or perforation, concurrent use of aspirin, corticosteroids and/or an anticoagulant or high dose/multiple NSAID use. This injured worker has had chronic blood in the stool, diagnosis of internal hemorrhoids and irritable bowel syndrome. She has had in July of 2014 findings on endoscopy of gastritis. The use of PPI would be reasonable in this setting, but guidelines recommend a trial of Lansoprazole or Omeprazole prior to Nexium therapy. There is no mention of failure to Lansoprazole or Omeprazole and as such, this request is not medically necessary.

CMP: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medical Practice Standard of Care.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, specific drug list & adverse effects.

Decision rationale: According to the CA MTUS Chronic Pain Guidelines, routine suggested monitoring for G.I. labs, hypertensive profiles, diabetes monitoring, is not medically necessary. Medical practice standard of care makes it reasonable to require documentation of a clearly stated rationale identifying why laboratory tests are needed to support the medical necessity of laboratory tests. There is no clear rationale for the labs CMP, CBC, Lipase, and Amylase. Most recent endoscopy was normal. As such, the request is not medically necessary.

CBC: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medical Practice Standard of Care.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, specific drug list & adverse effects.

Decision rationale: According to the CA MTUS Chronic Pain Guidelines, routine suggested monitoring for G.I. labs, hypertensive profiles, diabetes monitoring, is not medically necessary. Medical practice standard of care makes it reasonable to require documentation of a clearly stated rationale identifying why laboratory tests are needed to support the medical necessity of laboratory tests. There is no clear rationale for the labs CMP, CBC, Lipase, and Amylase. Most recent endoscopy was normal. As such, the request is not medically necessary.

Amylase: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medical Practice Standard of Care.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, specific drug list & adverse effects.

Decision rationale: According to the CA MTUS Chronic Pain Guidelines, routine suggested monitoring for G.I. labs, hypertensive profiles, diabetes monitoring, is not medically necessary. Medical practice standard of care makes it reasonable to require documentation of a clearly stated rationale identifying why laboratory tests are needed to support the medical necessity of laboratory tests. There is no clear rationale for the labs CMP, CBC, Lipase, and Amylase. Most recent endoscopy was normal. As such, the request is not medically necessary.

Lipase: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medical Practice Standard of Care.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, specific drug list & adverse effects.

Decision rationale: According to the CA MTUS Chronic Pain Guidelines, routine suggested monitoring for G.I. labs, hypertensive profiles, diabetes monitoring, is not medically necessary. Medical practice standard of care makes it reasonable to require documentation of a clearly stated rationale identifying why laboratory tests are needed to support the medical necessity of laboratory tests. There is no clear rationale for the labs CMP, CBC, Lipase, and Amylase. Most recent endoscopy was normal. As such, the request is not medically necessary.

Retro: Body composition study done 06/16/2015: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Guideline Clearinghouse.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Search of National Guideline Clearinghouse.

Decision rationale: A search of the National Guideline Clearinghouse provided guidelines titled "The official positions of the International Society for Clinical Densitometry: indications for use and reporting DXA for body composition" which state DXA total body composition with regional analysis can be used in the following conditions: In patients living with HIV to assess fat distribution in those using antiretroviral agents associated with a risk of lipoatrophy (currently stavudine and zidovudine); in obese patients undergoing bariatric surgery (or medical, diet, or weight loss regimens with anticipated large weight loss) to assess fat and lean mass changes when weight loss exceeds approximately 10%; and in patients with muscle weakness or poor physical functioning to assess fat and lean mass. The injured worker does not have HIV, critical illness, or any condition to warrant a body composition study at this time. This request is not medically necessary.