

Case Number:	CM15-0090898		
Date Assigned:	05/15/2015	Date of Injury:	07/12/2007
Decision Date:	07/08/2015	UR Denial Date:	04/16/2015
Priority:	Standard	Application Received:	05/11/2015

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

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 64 year old female injured worker suffered an industrial injury on 07/12/2007. The diagnoses included complex regional pain syndrome, cervical and lumbar radiculopathy. The injured worker had been treated with home exercise program, medications, cervical fusion. On 3/6/2015 the treating provider reported cervical radicular pain, lumbar radicular pain, bilateral knee pain, anxiety, depression and sleep disturbance. The pain was rated as 7/10. On exam, there was restricted cervical and lumbar range of motion with gait impairment. The treatment plan included Valsartan, Floranex, Aspirin, Ranitidine and Dexilant.

IMR ISSUES, DECISIONS AND RATIONALES

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

Valsartan 80mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation US National Library of Medicine/National Institutes of Health, MedLine Plus.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disability guidelines Diabetes (Type 1, 2 and Gestational chapter, Hypertension Treatment.

Decision rationale: Based on the 2/17/15 progress report provided by the treating physician, this patient presents with worsening hypertension, improved acid reflux, unchanged quality of sleep, and nausea without vomiting and without chills. The treater has asked for Valsartan 80MG #30 on 2/17/15. The request for authorization was not included in provided reports. The patient is s/p right knee arthroscopy of unspecified date per 2/17/15 report, and is s/p cervical spine fusion of unspecified levels from 7/16/14 according to 3/6/15 report. The patient has a dry cough with hypertension medication per 2/17/15 report. The patient still claims her blood pressure at home is 130/80-90 mmHg per 2/17/15 report. The patient also complains of neck pain rated 7/10 on VAS scale, lumbar radicular pain, and bilateral knee pain per 3/6/15 report. The patient's current medications are Dexilant, Ranitidine, Probiotics, ASA, and Diovan per 2/17/15 report. The patient's work status is temporarily totally disabled as of 1/13/15 report. MTUS and ACOEM Guidelines are silent on this issue. ODG Guidelines, chapter "Diabetes (Type 1, 2 and Gestational" and topic "Hypertension Treatment", state that "After Lifestyle (diet & exercise) modifications: (1) First line, 1st choice, Renin-angiotensin-aldosterone system blockers: ACE inhibitors (angiotensin-converting enzyme inhibitor): Benazepril (Lotensin); Captopril (Capoten); Enalapril (Vasotec); Lisinopril (Zestril); Ramipril (Altace), Angiotensin II receptor blocker (ARBs): Losartan (Cozaar); Olmesartan (Benicar); Valsartan (Diovan)." Valsartan has been prescribed in progress reports dated 2/17/15. The patient was taking Symvastatin per 4/22/14 report, but the efficacy is not mentioned. Medical records do not discuss hypertension or the prescribed anti-hypertension medication. ODG guidelines would consider this medication as a "First line, 1st choice for hypertension." The blood pressure of the patient was noted as 163/89 mmHg per 2/17/15 report. However, the efficacy of the blood pressure medication is not noted in provided reports. Also, the patient states the blood pressure at home is 130/80-90 per 2/17/15 report. As the medical necessity of the medication is not established, the request IS NOT medically necessary.

Floranex #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 Journal Therapeutic Advanced Gastroenterology 2010; 3 (5): 307-319. Use of Probiotics in Gastrointestinal Disorders.

Decision rationale: Based on the 2/17/15 progress report provided by the treating physician, this patient presents with worsening hypertension, improved acid reflux, unchanged quality of sleep, and nausea without vomiting and without chills. The treater has asked for Floranex #60 on 2/17/15. The request for authorization was not included in provided reports. The patient is s/p right knee arthroscopy of unspecified date per 2/17/15 report, and is s/p cervical spine fusion of unspecified levels from 7/16/14 according to 3/6/15 report. The patient has a dry cough with hypertension medication per 2/17/15 report. The patient still claims her blood pressure at home

is 130/80-90 mmHg per 2/17/15 report. The patient also complains of neck pain rated 7/10 on VAS scale, lumbar radicular pain, and bilateral knee pain per 3/6/15 report. The patient's current medications are Dexilant, Ranitidine, Probiotics, ASA, and Diovan per 2/17/15 report. The patient's work status is temporarily totally disabled as of 1/13/15 report. While MTUS and ODG guidelines do not specifically address the use of probiotic therapy for the treatment of gastrointestinal complaints, an article by published in the journal Therapeutic Advanced Gastroenterology 2010; 3 (5): 307-319. Use of Probiotics in Gastrointestinal Disorders by Elizabeth C. Verna, MD, MSc, Susan Lucak has the following: "The effect of probiotics on other GI disorders have also been studied, including lactose intolerance, Helicobacter pylori infection, microscopic colitis, prevention and treatment of diverticulitis, and even colon cancer prevention. The studies have been small and meta-analyses are too variable to draw firm conclusions of benefit...When added to standard therapy, probiotics do not provide additional benefit compared with standard therapy alone. Most probiotics tested to date are not more effective than placebo in inducing or maintaining IBD remission." Treater has not provided a reason for the request. Unspecified probiotics was prescribed to the patient on 2/17/15, per provided medical reports. Probiotics do not meet the criteria set by ODG for medical foods. Furthermore, there are no peer-reviewed studies available, which establish the efficacy of probiotic therapy as an effective treatment. Therefore, this request IS NOT medically necessary.

Aspirin 81mg EC #30: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatory medications Medications for chronic pain Page(s): 22, 60.

Decision rationale: Based on the 2/17/15 progress report provided by the treating physician, this patient presents with worsening hypertension, improved acid reflux, unchanged quality of sleep, and nausea without vomiting and without chills. The treater has asked for Aspirin 81MG EC #30 on 2/17/15. The request for authorization was not included in provided reports. The patient is s/p right knee arthroscopy of unspecified date per 2/17/15 report, and is s/p cervical spine fusion of unspecified levels from 7/16/14 according to 3/6/15 report. The patient has a dry cough with hypertension medication per 2/17/15 report. The patient still claims her blood pressure at home is 130/80-90 mmHg per 2/17/15 report. The patient also complains of neck pain rated 7/10 on VAS scale, lumbar radicular pain, and bilateral knee pain per 3/6/15 report. The patient's current medications are Dexilant, Ranitidine, Probiotics, ASA, and Diovan per 2/17/15 report. The patient's work status is temporarily totally disabled as of 1/13/15 report. MTUS Chronic Pain Medical Treatment Guidelines, pg 22 for Anti-inflammatory medications states: Anti-inflammatories are the traditional first line of treatment, to reduce pain so activity and functional restoration can resume, but long-term use may not be warranted. A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain concludes that available evidence supports the effectiveness of non-selective nonsteroidal anti-inflammatory drugs (NSAIDs) in chronic LBP and of antidepressants in chronic LBP. MTUS p60 also states, "A record of pain and function with the medication should be recorded," when medications are used for chronic pain. The patient is taking Aspirin per

4/22/14 and 2/17/15 reports. The patient is taking Diclofenac per 11/26/14 report. Review of reports do not show any documentation of Aspirin's effectiveness. The 10/15/14 report states that "the patient was advised to avoid NSAIDs." Therefore, the request IS NOT medically necessary.

Ranitidine 150mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 69.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs against both GI and cardiovascular risk Page(s): 69.

Decision rationale: Based on the 2/17/15 progress report provided by the treating physician, this patient presents with worsening hypertension, improved acid reflux, unchanged quality of sleep, and nausea without vomiting and without chills. The treater has asked for Ranitidine 150MG #30 on 2/17/15. The request for authorization was not included in provided reports. The patient is s/p right knee arthroscopy of unspecified date per 2/17/15 report, and is s/p cervical spine fusion of unspecified levels from 7/16/14 according to 3/6/15 report. The patient has a dry cough with hypertension medication per 2/17/15 report. The patient still claims her blood pressure at home is 130/80-90 mmHg per 2/17/15 report. The patient also complains of neck pain rated 7/10 on VAS scale, lumbar radicular pain, and bilateral knee pain per 3/6/15 report. The patient's current medications are Dexilant, Ranitidine, Probiotics, ASA, and Diovan per 2/17/15 report. The patient's work status is temporarily totally disabled as of 1/13/15 report. MTUS Guidelines page 69 states, "clinicians should weigh the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: 1. Ages greater than 65 years. 2. History of peptic ulcer, GI bleeding, or perforation. 3. Concurrent use of ASA, corticosteroids, and/or an anticoagulant. 4. High-dose multiple NSAID." "Treatment of dyspepsia secondary to NSAID therapy: Stop the NSAID, switch to a different NSAID, or consider H2 receptor antagonist or a PPI." The patient was prescribed Omeprazole and Diclofenac per 11/26/14 report. Patient is taking Aspirin and Dexilant as of requesting 2/17/15 report. However, there are no discussions regarding the efficacy of prior use of a PPI. There are no GI symptoms described and no GI assessment is provided. Due to lack of documentation of prior use of PPIs, the requested ranitidine IS NOT medically necessary.

Dexilant 60mg DR #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68.

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

Decision rationale: Based on the 2/17/15 progress report provided by the treating physician, this patient presents with worsening hypertension, improved acid reflux, unchanged quality of sleep, and nausea without vomiting and without chills. The treater has asked for Dexilant 60MG

DR #30 on 2/17/15. The request for authorization was not included in provided reports. The patient is s/p right knee arthroscopy of unspecified date per 2/17/15 report, and is s/p cervical spine fusion of unspecified levels from 7/16/14 according to 3/6/15 report. The patient has a dry cough with hypertension medication per 2/17/15 report. The patient still claims her blood pressure at home is 130/80-90 mmHg per 2/17/15 report. The patient also complains of neck pain rated 7/10 on VAS scale, lumbar radicular pain, and bilateral knee pain per 3/6/15 report. The patient's current medications are Dexilant, Ranitidine, Probiotics, ASA, and Diovan per 2/17/15 report. The patient's work status is temporarily totally disabled as of 1/13/15 report. MTUS guidelines page 69 recommends prophylactic use of PPI's when appropriate GI assessments have been provided. The patient must be determined to be at risk for GI events, such as age > 65 years, history of peptic ulcer, GI bleeding or perforation, concurrent use of ASA, corticosteroids, and/or an anticoagulant, or high dose/multiple NSAID. 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." The patient was prescribed Omeprazole and Diclofenac per 11/26/14 report. Patient is taking Aspirin and Dexilant as of requesting 2/17/15 report. However, there are no discussions regarding the efficacy of prior use of Dexilant. There are no GI symptoms described and no GI assessment is provided. Due to the lack of documentation of its prior efficacy, the requested Dexilant IS NOT medically necessary.