

Case Number:	CM14-0006179		
Date Assigned:	03/03/2014	Date of Injury:	03/18/2010
Decision Date:	06/30/2014	UR Denial Date:	12/16/2013
Priority:	Standard	Application Received:	01/16/2014

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 Anesthesiology, Pain 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 injured worker is a 46 year old female injured on 03/18/10 due to an undisclosed mechanism of injury. Current diagnoses include status post right ankle surgery, left knee arthralgia, internal derangement, medial meniscus disease, chronic cervicothoracolumbar back ache, recurrent myofascial strain, dependence on medications, and conservative therapy. The injured worker utilizes Percocet, Ambien, Norco, Miralax, Naproxen, and omeprazole, and proprietary medical food products. The injured worker underwent a lumbar epidural steroid injection on 08/23/13 and a cervical epidural steroid injection on 09/13/13. The clinical note dated 11/27/13 indicates the injured worker presented complaining of constant neck, mid back, and low back pain with left knee and right ankle pain. The injured worker reported an increase in pain due to recent cold weather. The injured worker rated his pain at 10/10 without medication and 7/10 with the use of medications. The injured worker also reported the use of topical medications decreased pain and increased sleep. Objective findings include decreased cervical range of motion and tenderness to the cervical spine on palpation. Lumbar range of motion was decreased, tenderness of the lumbar spine with spasms, and left lower extremity sensation decreased at L3-S1 on examination. The injured worker was prescribed Percocet 10/325mg, Ambien 10mg, Norco 10/325mg, Miralax 1 bottle, Colace 100mg, Theramine, Sentra AM, Sentra PM, Gabadone, Naproxen Sodium 550mg, Omeprazole 20mg, and Terocin pain patch box #2. The initial requests for 1 Miralax bottle, Colace 100mg #100, Naproxen Sodium 550mg #60, Omeprazole 20mg #90, Theramine, Sentra AM, Sentra PM, Terocin patch box #2, and Gabadone were initially non-certified on 12/16/13.

IMR ISSUES, DECISIONS AND RATIONALES

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

ONE MIRALAX BOTTLE: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.pdr.net/drug-summary/miralax?druglabelid=824&id=272>.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 77.

Decision rationale: As noted on page 77 of the Chronic Pain Medical Treatment Guidelines, prophylactic constipation measures should be initiated when long-term opioid medications are to be utilized; however, there is no indication in the documentation that attempts were made and failed at first-line treatment options to include proper diet, activity modification and increased fluid intake. Additionally, there is indication that the patient cannot utilize the readily available over-the-counter formulation of the medication. Additionally, there is no indication in the documentation of complaints of constipation requiring pharmaceutical intervention. As such, the request for one Miralax bottle cannot be recommended as medically necessary.

COLACE 100 MG #100: 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/pubmedhealth/pmh0000100/>.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 77.

Decision rationale: As noted on page 77 of the Chronic Pain Medical Treatment Guidelines, prophylactic constipation measures should be initiated when long-term opioid medications are to be utilized; however, there is no indication in the documentation that attempts were made and failed at first-line treatment options to include proper diet, activity modification and increased fluid intake. Additionally, there is indication that the patient cannot utilize the readily available over-the-counter formulation of the medication. Additionally, there is no indication in the documentation of complaints of constipation requiring pharmaceutical intervention. As such, the request for Colace 100 MG #100 cannot be recommended as medically necessary.

NAPROXEN SODIUM 550 MG #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS (Non-Steroidal Anti-Inflammatory Drugs) Page(s): 70.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 70.

Decision rationale: As noted on page 70 of the Chronic Pain Medical Treatment Guidelines, NSAIDs are recommended as a second-line treatment after acetaminophen for acute exacerbations of chronic pain. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute lower back pain. Package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile (including liver and renal function tests). There is no documentation that these monitoring recommendations have been performed and the patient is being monitored on a routine basis. Additionally, it is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time. As such, the request for Naproxen Sodium 550 MG #60 cannot be established as medically necessary.

OMEPRAZOLE 20 MG #90: Upheld

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

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

Decision rationale: As noted in the Official Disability Guidelines - Online version, Pain Chapter, proton pump inhibitors are indicated for patients at intermediate and high risk for gastrointestinal events with concurrent use of non-steroidal anti-inflammatory drug use. Risk factors for gastrointestinal events include 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 (e.g., NSAID + low-dose ASA). There is no indication that the patient is at risk for gastrointestinal events requiring the use of proton pump inhibitors. Furthermore, long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture. As such, the request for Omeprazole 20 MG #90 cannot be established as medically necessary.

THERAMINE: 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 - 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 (Chronic), Medical Foods.

Decision rationale: As noted in the Pain Chapter of the Official Disability Guidelines, Theramine® is not recommended for use in chronic pain management. Theramine® is a medical food that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. There are no high quality studies that support the use of Theramine. Additionally, the use of herbal medicines

or medical foods is not recommended. There is no indication in the documentation that the patient has failed previous prescription medications or has obvious contraindications limiting prescribing to medical foods. As such, the request for nutraceutical medication Theramine cannot be recommended as medically necessary.

SENTRA AM: 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 - 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 (Chronic), Medical Food.

Decision rationale: As noted in the Pain chapter of the Official Disability Guidelines - Online version, the use of herbal medicines or medical foods is not recommended. There is no indication in the documentation that the patient has failed previous prescription medications or has obvious contraindications limiting treatment options to medical foods. As such, the request for Sentra AM cannot be recommended as medically necessary.

SENTRA PM: 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); 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 & Stress.

Decision rationale: As noted in the Pain chapter of the Official Disability Guidelines - Online version, the use of herbal medicines or medical foods is not recommended. Sentra PM™ is a medical food from [REDACTED] intended for use in management of sleep disorders associated with depression, that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. There is no indication in the documentation that the patient has failed previous prescription medications or has obvious contraindications. As such, the request for Sentra PM cannot be recommended as medically necessary.

TEROCIN PATCH BOX #2: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

Decision rationale: As noted on page 111 of the Chronic Pain Medical Treatment Guidelines, the safety and efficacy of compounded medications has not been established through rigorous clinical trials. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is no indication in the documentation that these types of medications have been trialed and/or failed. Therefore Terocin Patch Box #2 cannot be recommended as medically necessary as it does not meet established and accepted medical guidelines.

GABADONE: 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 - 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 (Chronic), Gabadone.

Decision rationale: As noted in the Pain chapter of the Official Disability Guidelines - Online version, the use of herbal medicines or medical foods is not recommended. GABAdone™ is a medical food from [REDACTED], that is a proprietary blend of Choline Bitartrate, Glutamic Acid, 5-Hydroxytryptophan, and GABA. It is intended to meet the nutritional requirements for inducing sleep, promoting restorative sleep and reducing snoring in patients who are experiencing anxiety related to sleep disorders. There is no indication in the documentation that the patient has failed previous prescription medications or has obvious contraindications. As such, the request for GABAdone cannot be recommended as medically necessary.