

Case Number:	CM14-0141394		
Date Assigned:	09/10/2014	Date of Injury:	06/26/2003
Decision Date:	02/13/2015	UR Denial Date:	08/21/2014
Priority:	Standard	Application Received:	09/02/2014

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 Internal Medicine, has a subspecialty in Hospice and Palliative Medicine and is licensed to practice in Pennsylvania. 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 66-year-old gentleman with a date of injury of 06/26/2003. The submitted and reviewed documentation did not identify the mechanism of injury. Treating physician notes dated 07/14/2014 and 07/23/2014 indicated the worker was experiencing constipation from medication, vertigo, weight gain, depressed mood, and lower back pain that went into the left leg. Documented examinations described tenderness where the lower back meets the pelvis on both sides, decreased sensation following the paths of the L4-S1 spinal nerves, decreased motion in the back joints, decreased reflexes at the ankles, and mildly decreased ankle strength. The submitted and reviewed documentation concluded the worker was suffering from GERD, hypertension, chronic regional pain syndrome, constipation, post-operative left leg radiculopathy, coccydynia, and L5-S1 pseudoarthrosis. Treatment recommendations included medications, trigger point injection, thiamine medical food, and follow up care. A Utilization Review decision was rendered on 08/21/2014 recommending non-certification for an indefinite supply of lactulose with an unspecified dose, Dulcolax (bisacodyl) with an unspecified dose, Ultram (tramadol) 50mg, and the medical food Thiamine.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lactulose: 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, Opioid Induced Constipation.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-95. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Lactulose: Drug information; Topic 9543, version 91.0, Up-to-date, accessed 02/09/2015.

Decision rationale: The MTUS Guidelines recognize that constipation is a very common negative effect from the use of opioid medications. The Guidelines encourage its treatment before it develops as well as if it occurs. Lactulose is an osmotic laxative and an ammonium detoxicant. It is FDA-approved for the treatment of constipation and for the prevention and treatment of portal systemic encephalopathy. The submitted and reviewed documentation concluded the worker was suffering from GERD, hypertension, chronic regional pain syndrome, constipation, post-operative left leg radiculopathy, coccydynia, and L5-S1 pseudoarthrosis. The request was made for an indefinite supply of medication at an unspecified dose, which does not account for potential changes in the worker's overall health or treatment needs. For these reasons, the current request for an indefinite supply of lactulose with an unspecified dose is not medically necessary.

Dulcolax: 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, Opioid Induced Constipation.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-95. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Bisacodyl: Drug information; Topic 8815, version 97.0, Up-to-date, accessed 02/09/2015

Decision rationale: The MTUS Guidelines recognize that constipation is a very common negative effect from the use of opioid medications. The Guidelines encourage its treatment before it develops as well as if it occurs. Dulcolax (Bisacodyl) is a stimulant laxative. It is FDA-approved for the treatment of constipation. The submitted and reviewed documentation concluded the worker was suffering from GERD, hypertension, chronic regional pain syndrome, constipation, post-operative left leg radiculopathy, coccydynia, and L5-S1 pseudoarthrosis. The request was made for an indefinite supply of medication at an unspecified dose, which does not account for potential changes in the worker's overall health or treatment needs. For these reasons, the current request for an indefinite supply of Dulcolax (Bisacodyl) with an unspecified dose is not medically necessary.

Ultram 50mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Specific Drug List Page(s): 93-94.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids; Weaning of Medications Page(s): 74-95; 124.

Decision rationale: Ultram (Tramadol) is a medication in the opioid class. The MTUS Guidelines stress the lowest possible dose of opioid medications should be prescribed to improve pain and function, and monitoring of outcomes over time should affect treatment decisions. Documentation of pain assessments should include the current pain intensity, the lowest intensity of pain since the last assessment, the average pain intensity, pain intensity after taking the opioid medication, the amount of time it takes to achieve pain relief after taking the opioid medication, the length of time the pain relief lasts, use and of drug screening with issues of abuse or addiction. Acceptable results include improved function, decreased pain, and/or improved quality of life. The MTUS Guidelines recommend opioids be continued when the worker has returned to work and if the worker has improved function and pain control. When these criteria are not met, an individualized taper is recommended. The submitted and reviewed documentation indicated the worker was experiencing constipation from medication, vertigo, weight gain, depressed mood, and lower back pain that went into the left leg. The documented pain assessments contained few of the elements encouraged by the Guidelines. Further, the request was made for an indefinite supply of medication at an unspecified dose, which does not account for potential changes in the worker's overall health or treatment needs. For these reasons, the current request for an indefinite supply of Ultram (Tramadol) 50mg is not medically necessary. While the Guidelines support the use of an individualized taper to avoid withdrawal effects, the risks of continued use significantly outweigh the benefits in this setting based on the submitted documentation, and a wean should be able to be completed with the medication available to the worker.

Theramine medical food: 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 Other Medical Treatment Guideline or Medical Evidence: Theramine product information, Accessed 08/14/2014
<http://www.nutrientpharmacology.com/PDFs/monographs/theramine-monograph.pdf>; accessed 02/09/2015

Decision rationale: The MTUS Guidelines are silent on this issue. Theramine is a medicinal food that contains L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan, GABA, L-serine, grape-seed extract, cinnamon bark, whey protein, cocoa, and metabrine. The MTUS Guidelines require that the use of treatments be scientific and evidence-based. The submitted and reviewed documentation concluded the worker was suffering from GERD, hypertension, chronic regional pain syndrome, constipation, post-operative left leg

radiculopathy, coccydynia, and L5-S1 pseudoarthrosis. A review of the literature revealed no vigorous, peer-reviewed studies demonstrating a clear scientific benefit for using Theramine in the treatment of the worker's active issues. There was no discussion describing special circumstances that sufficiently supported this request. In the absence of such evidence, the current request for the medical food Theramine is not medically necessary.