

Case Number:	CM14-0123755		
Date Assigned:	08/08/2014	Date of Injury:	06/13/2002
Decision Date:	10/14/2014	UR Denial Date:	07/11/2014
Priority:	Standard	Application Received:	08/05/2014

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 as a subspecialty in Pain Management and is licensed to practice in Nevada. 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 54 year old female who reported an injury to her neck on 6/13/2002. No description of the initial injury was included in the documentation. The clinical note dated 12/27/13 indicates the injured worker complaining of worsening neck pain secondary to the onset of colder weather. The injured worker reported radiating pain from the neck into both upper extremities. The injured worker rated the pain as 5-10/10. The utilization review dated 05/09/14 resulted in non-certifications for the use of Gabadone, Theramine, and Trepadone as no evidence exists confirming the safety and efficacy of the use of medical foods. The clinical note dated 03/10/14 indicates the injured worker continuing with neck pain with radiating pain to the upper extremities. The injured worker stated that when she coughs, the pain level increases dramatically. The injured worker rated the pain as 4-10/10. The clinical note dated 06/19/14 indicates the injured worker stated the continued use of Nucynta was helping her function. The injured worker reported near daily headaches.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gabadone # 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

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, GABAdone

Decision rationale: The request for Gabadone #60 is not medically necessary. The injured worker has complaints of ongoing neck pain with radiating pain to the upper extremities. The safety and efficacy of the use of medical foods has not been confirmed as no high quality studies have been published in peer reviewed literature supporting the use of these items. Without supporting evidence in place, this request is not medically necessary.

Theramine # 120: Upheld

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

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, Theramine®

Decision rationale: The request for Theramine #120 is not medically necessary. The injured worker has complaints of ongoing neck pain with radiating pain to the upper extremities. The safety and efficacy of the use of medical foods has not been confirmed as no high quality studies have been published in peer reviewed literature supporting the use of these items. Without supporting evidence in place, this request is not medically necessary.

Trepidone # 120: Upheld

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

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, Trepadone®

Decision rationale: The request for Trepadone #120 is not medically necessary. The injured worker has complaints of ongoing neck pain with radiating pain to the upper extremities. The safety and efficacy of the use of medical foods has not been confirmed as no high quality studies have been published in peer reviewed literature supporting the use of these items. Without supporting evidence in place, this request is not medically necessary.

Colace 100mg # 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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Non-MTUS Other Medical Treatment Guideline or Medical Evidence: 1.) Dharmananda, Subhuti. "safety issues affecting herbs: How Long can Stimulant Laxatives be Used?". Institute for Traditional 2.) Anita Hickey MD, Ian Laughlin MD. Essentials of Pain Management. 2011, pp 725-746. 20 Dec 2010. Drug Formulary for Pain Management.

Decision rationale: The use of Colace is indicated for injured workers with ongoing complaints of constipation or the continued use of opioid therapy. No information was submitted regarding the injured worker's ongoing use of opioids. Additionally, no information was submitted regarding the injured worker's ongoing complaints of constipation. Without these factors in place, this request is not medically necessary.

Fluriflex Ointment: Upheld

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

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

Decision rationale: 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. Further, CA MTUS, Food and Drug Administration, and Official Disability Guidelines require that all components of a compounded topical medication be approved for transdermal use. This compound contains cyclobenzaprine which have not been approved for transdermal use. In addition, there is no evidence within the medical records submitted that substantiates the necessity of a transdermal versus oral route of administration. Therefore this compound is not medically necessary as it does not meet established and accepted medical guidelines.

Nucynta IR 75mg # 120: Upheld

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

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, Tapentadol (Nucynta®)

Decision rationale: The use of Nucynta is recommended only as a 2nd line therapy for injured workers who develop intolerable adverse effects with 1st line opioids. No information was submitted regarding the injured worker's previous trials or the effectiveness of the previous opioid trials. Given this factor, the request is not medically necessary.

Skelaxin 800mg # 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

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, Skelaxin® (metaxalone)

Decision rationale: Muscle relaxants are recommended as a second-line option for short-term treatment of acute low back pain and for short-term treatment of acute exacerbations in injured workers with chronic low back pain. Studies have shown that the efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Based on the clinical documentation, the injured worker has exceeded the 4 week window for acute management also indicating a lack of efficacy if being utilized for chronic flare-ups. As such, the medical necessity of this medication cannot be established at this time.