MAXIMUS Federal Services

Case Number:	CM14-0146359		
Date Assigned:	09/12/2014	Date of Injury:	02/06/2005
Decision Date:	10/16/2014	UR Denial Date:	08/04/2014
Priority:	Standard	Application Received:	09/09/2014

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 and Pain Medicine and is licensed to practice in Florida. 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 male who reported an injury on 02/06/2005 due to an unknown mechanism. Diagnosis was lumbar radiculitis. Physical examination on 07/16/2014 revealed complaints of low back pain that radiated to the lower extremities with numbness and tingling. The pain was rated a 10/10. Examination revealed lumbar range of motion, flexion was to 50 degrees, extension was to 10 degrees, right lateral flexion was to 15 degrees, and left lateral flexion was to 15 degrees. Straight leg raise was positive bilaterally. Treatment plan was to continue medications as directed. The rationale and Request for Authorization were not submitted.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine #90: 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, Medical Food

Decision rationale: The request for Theramine #90 is not medically necessary. The Official Disability Guidelines state that medical food is not recommended for chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. FDA defines a medical food as "a food which is formulated to be consumed or administered enterally 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." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. There was no frequency indicated for this medical food. There were no significant factors provided to justify the use outside of current guidelines. Therefore, this request is not medically necessary.

Sentra AM, #60 and Sentra PM, #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, Medical Food

Decision rationale: The request for Sentra AM, #60 and Sentra PM, #60 is not medically necessary. The Official Disability Guidelines state that medical food is not recommended for chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. FDA defines a medical food as "a food which is formulated to be consumed or administered enterally 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." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. There was no frequency indicated for this medical food. There were no significant factors provided to justify the use outside of current guidelines. Therefore, this request is not medically necessary.

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, Medical Food

Decision rationale: The request for Gabadone #60 is not medically necessary. The Official Disability Guidelines state that medical food is not recommended for chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. FDA defines a medical food as "a food which is formulated to be consumed or administered enterally 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." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. There was no frequency indicated for this medical food. There were no significant factors provided to justify the use outside of current guidelines. Therefore, this request is not medically necessary.

Trepadone #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment 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, Medical Food

Decision rationale: The request for Trepadone #90 is not medically necessary. The Official Disability Guidelines state that medical food is not recommended for chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. FDA defines a medical food as "a food which is formulated to be consumed or administered enterally 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." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. There was no frequency indicated for this medical food. There were no significant factors provided to justify the use outside of current guidelines. Therefore, this request is not medically necessary.

Xolido 2% cream: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Drug.com: http://dailymed.nlm.nih.gov/dailymed/druginfo.cfm?setid=f2b463d7-3fcf-4b2c-8ba2-8

Decision rationale: The decision for Xolido 2% Cream is not medically necessary. The California Medical Treatment Utilization Schedule, ACOEM and ODG do not address this request. Dailymed.com states that this is an over the counter medication and approved by the FDA> However, it does contain lidocaine and is used topically for pain relief. The CA MTUS does address lidocaine as it may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressant or an AED such as gabapentin or Lyrica). The efficacy of this medication was not reported and the request does not indicate a frequency for the medication. Therefore, this medication is not medically necessary.