

Case Number:	CM13-0021512		
Date Assigned:	11/13/2013	Date of Injury:	07/10/2009
Decision Date:	01/27/2014	UR Denial Date:	08/15/2013
Priority:	Standard	Application Received:	09/09/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Orthopedic Surgery, has a Spine Fellowship, and is licensed to practice in New Hampshire, New York, and Washington. 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 physician 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:

This patient is a 36-year-old male injured on 7/10/2009. He has chronic back and right knee pain. He had previous lumbar fusion surgery, and recent x-rays do not show any evidence of hardware failure in the lumbar spine. Excellent hardware position and alignment is noted at the L5-S1 fusion. The patient has been referred to a psychologist and physical therapy has been ordered. Treatment has included medications. The knee pain has been attributed to meniscal tear and Baker's cyst. Back pain symptom cause remains unclear, and mention is given to possible painful hardware. Notes from March 2013 indicate that the back pain was improving. At issue is whether or not Sintralyne (30 tablets) is medically necessary for this patient at this time.

IMR ISSUES, DECISIONS AND RATIONALES

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

Sintralyne, #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation FDA website.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation PUBMED Lit Review:: Sintralyne-pm

(melatonin/gamma-aminobutyric acid/herbal complex no.183). The following term was not found in PubMed: syntralyn. No items found.

Decision rationale: Sintralyn-pm (melatonin/gamma-aminobutyric acid/herbal complex no.183) is not addressed by MTUS Guidelines. Significant guidelines for the medical appropriateness and safety of medical foods has not been established. There are no treatment guidelines that recommend the use of medical foods in the treatment of any condition described in this patient. Recent documentation indicates that the patient's back pain was improving. The use of Sintralyn is experimental and not supported by any peer-reviewed literature or any published medical guidelines.