

Case Number:	CM15-0088289		
Date Assigned:	05/12/2015	Date of Injury:	09/25/1990
Decision Date:	06/16/2015	UR Denial Date:	04/07/2015
Priority:	Standard	Application Received:	05/07/2015

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 57-year-old female, who sustained an industrial injury on September 25, 1990. She reported chronic migraine. The injured worker was diagnosed as having chronic migraine and fibromyalgia state. Treatment to date has included diagnostic studies, physical therapy, Botox injections, medications and work restrictions. Currently, the injured worker complains of continued chronic migraines and fibromyalgia state. The injured worker reported an industrial injury in 1990, resulting in the above noted pain. She was treated conservatively without complete resolution of the pain. It was noted she required daily pain medications chronically to remain functional. She reported a decrease from 24 headaches per 30 days to 15 per 30 days with Botox injections; she received Botox injections on March 4, 2015 per protocol. Evaluation on April 29, 2015, revealed continued pain as noted. Medications were renewed and requested.

IMR ISSUES, DECISIONS AND RATIONALES

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

Xyrem 500mg/ml 4.75: 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.

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, sodium oxybate?Xyrem.

Decision rationale: Per the 04/29/15 report by [REDACTED], the patient presents with migraine headaches. The 03/30/15 letter by the requesting physician, [REDACTED] /Rheumatology specialty, states the patient presents with increasing flare-ups of Fibromyalgia. The current request is for XYREM 500 mg/ml 4.75. The 04/07/15 utilization review modified this request to 2 x/night at bedtime for one month. As presented above, this request does not include a quantity. The reports do not state if the patient is currently working. ODG, Pain Chapter, sodium oxybate- Xyrem, states, "Not recommended for fibromyalgia. The FDA rejected sodium oxybate (Xyrem) for the treatment of fibromyalgia. There is substantial risk of abuse because the drug is the same as GHB (gamma-Hydroxybutyric acid), the "date-rape" drug. Currently, the drug is approved for the treatment of excessive daytime sleepiness and cataplexy associated with narcolepsy. The FDA said there was lack of convincing evidence that the risks involved in releasing the drug to a large population were balanced by its effectiveness in treating fibromyalgia-related pain and sleeping problems, because there is no data to show that it is better than existing medications." The requesting physician states on 03/30/15 that this drug is for daytime somnolence that has been increasing due to increasing fibromyalgia flare-ups. The treater further states the patient is unable to taper the medication and believes it would be detrimental to attempt further taper as the patient was extremely stable for multiple years prior to the taper attempt. In this case, ODG guidelines state the requested medication is indicated for excessive daytime sleepiness and cataplexy associated with Narcolepsy. Recent reports provided for review provide no evidence of narcolepsy for this patient. Furthermore, ODG specifically does not recommend Xyrem for Fibromyalgia. The request IS NOT medically necessary.