

Case Number:	CM15-0017121		
Date Assigned:	02/04/2015	Date of Injury:	09/23/2010
Decision Date:	04/17/2015	UR Denial Date:	01/10/2015
Priority:	Standard	Application Received:	01/28/2015

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: New York, Tennessee
 Certification(s)/Specialty: Emergency Medicine

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 49 year old female, who sustained an industrial injury on September 23, 2010. The diagnoses have included repetitive trauma with cervical spine, right shoulder sprain/strain with impingement, thoracic sprain/strain, and anxiety and depression with loss of libido. Treatment to date has included extracorporeal shockwave treatment, urine drug testing, MRI, rest, ice, non-steroidal anti-inflammatory medication, elastic elbow brace, steroid injections, home exercise program, work modifications, physical therapy, an interferential unit, and medications which included pain, muscle relaxant, proton pump inhibitor, sleeping, and non-steroidal anti-inflammatory medications. On June 7, 2013, the treating physician noted the injured worker had difficulty sleeping. The treatment plan included sleep medication. On July 12, 2013, the treating physician noted persistent neck and right shoulder pain that worsens with activities. Medications helped to decrease the pain. The physical exam revealed continued cervical pain with painful and moderately decreased range of motion. The right shoulder was extremely tender at the greater tuberosity and acromioclavicular joint. The range of motion was mildly decreased. The treatment plan included continuing medications and home exercises. On January 10, 2015, Utilization Review non-certified a retrospective prescription for Sintralyn-PM (DOS: 7/3/13 and 8/2/13), noting the lack of indication of a diagnosis of insomnia and no indication of why this medication was provided. In addition, one component in the medication, gamma-aminobutyric acid/herbal complex no. 183, is not recommended by the guidelines do not recommend. Therefore, the medication is not recommended. The California Medical Treatment

Utilization Schedule (MTUS), Chronic Pain and the Official Disability Guidelines (ODG) were cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective request for Sintralyn-PM date of service 7/3/2013 and 8/2/2013: Upheld

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

<http://www.connectrx.com/connectrx/productb/pharmaceutica-n/sintralyn-pm-melatonin-gamma-aminobutyric-acid-herbal-complex-no183> 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: Pain, melatonin, medical food.

Decision rationale: Sintralyn is a compounded medication containing melatonin and gamma-aminobutyric acid (GABA). Melatonin is recommended for delayed sleep phase syndrome and rapid eye movement sleep behavior disorders. There is also some suggestion that it can have an analgesic effect, but current research is largely in the experimental phases. GABA is the derivative of glutamic acid and ornithine. It does not cross the blood-brain barrier so taking this orally does not increase brain levels. Therefore taking the supplement will not replicate drugs that do work by a GABA-related mechanism. In complimentary medicine settings, this supplement has been used for treatment of depression, bipolar disorder, seizures, premenstrual dysphoric disorder, and anxiety, although there is no quality evidence that GABA supplements have any effect on these conditions. It has also been suggested that GABA can improve sleep quality and improve cognitive function, but there is no scientific evidence to support these claims. There is some preliminary evidence that GABA can reduce blood pressure, but further studies are needed to allow for a recommendation for general use. It is not recommended. In this case there is no documentation that the patient has sleep disorder or is suffering from insomnia. In addition the guidelines state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." This medication contains drugs that are not recommended. Therefore the medication cannot be recommended. The request should not be authorized.