

Case Number:	CM13-0036267		
Date Assigned:	12/13/2013	Date of Injury:	03/10/2010
Decision Date:	05/30/2014	UR Denial Date:	10/03/2013
Priority:	Standard	Application Received:	10/18/2013

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 Occupational Medicine and is licensed to practice in California. 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:

Medical records from 2013 were reviewed and showed persistent right shoulder, right arm, right elbow and right hand pain graded 9-10/10 associated with tingling and numbness in the right upper extremity and intermittent sharp, shooting pain in the right hand. Physical examination showed right shoulder spasms, limitation of motion of the shoulder and dysesthesia to light touch in the right upper extremity. The patient was prescribed with amitriptyline, naproxen sodium, Savella and Dendracin cream. Utilization review dated October 3, 2013 denied the requests for Savella 25mg PO q12h #60 3 refills because it is not recommended as it is not FDA approved; and Dendracin cream because it contains 0.0375 percent of capsaicin which is not recommended.

IMR ISSUES, DECISIONS AND RATIONALES

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

SAVELLA 25MG P.O Q 12H #60 REFILLS 3: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Milnacipran (Ixel) Page(s): 62-63.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 62-63.

Decision rationale: According to CA MTUS Chronic Pain Medical Treatment Guidelines page 62-63, Milnacipran (Savella) is not recommended as it is not FDA approved and not available in

the US at this time. An FDA Phase III study demonstrated "significant therapeutic effects" of Milnacipran for treatment of fibromyalgia syndrome. In this case, the patient was diagnosed with Complex Regional Pain Syndrome (CPRS). Savella is currently not indicated for the treatment of this condition. Therefore, the request for Savella 25mg PO q12h #60 3 refills is not medically necessary.

DENDRACIN CREAM: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals, Topical Analgesics Page(s): 105, 112-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

Decision rationale: As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. Dendracin contains Methyl salicylate/capsaicin 0.0375%/Menthol. The California MTUS states that there are no current indications for a capsaicin formulation of 0.0375%. Regarding the Menthol component, CA MTUS does not cite specific provisions, but the ODG Pain Chapter states that the FDA has issued an alert in 2012 indicating that topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns. Any compounded product that contains at least one drug (drug class) that is not recommended is not recommended. In this case, the patient has been using Dendracin for pain however, this compound medication is not supported by guidelines. There is no discussion concerning the need for variance from the guidelines or failure of oral medications. Therefore the request for Dendracin is not medically necessary.