

<b>Case Number:</b>	CM14-0060580		
<b>Date Assigned:</b>	07/09/2014	<b>Date of Injury:</b>	01/06/2011
<b>Decision Date:</b>	09/08/2014	<b>UR Denial Date:</b>	04/24/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/01/2014

### 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, has a subspecialty in Pain Management and is licensed to practice in Tennessee. 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 patient is a 37-year-old male who has submitted a claim for left S1 radiculopathy, L4-5, L5-S1 disc disease with L5-S1 annular disruption, and medication-induced gastritis associated with an industrial injury date of 01/08/2011. Medical records from 04/22/2013 to 07/09/2014 were reviewed and showed that patient complained of low back pain graded 7/10 which radiates into bilateral lower extremities. Physical examination of the lumbar spine revealed limited lumbar ROM. Kemp's and SLR test on supine position were positive bilaterally. MMT of bilateral lower extremities was 5/5. MRI of the lumbar spine revealed L4-5 minor disc desiccation with neural foraminal narrowing, diffuse disc bulge material abutted S1 traversing nerve roots, mild defacement of anterior thecal sac, and mild bilateral facet hypertrophy. EMG/NCS study dated 05/20/2011 revealed left active S1 denervation. Treatment to date has included physical therapy, home exercise program, acupuncture, and pain medications. Utilization review dated 04/24/2014 denied the request for Capsaicin .025%/ Flurbiprofen .15%/ Tramadol 15%/ Menthol 2%/ Camphor 2% 240gms QTY: 3.00 and Amitriptyline 4%/ Dectromethorphan 15%/ Flurbiprofen 20% 240gm QTY 3.00 because insufficient large scale, long-term references showing the safety and efficacy of the requested prescription in this patient's clinical scenario were unavailable.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Capsaicin .025%/ Flurbiprofen .15%/ Tramadol 15%/ Menthol 2%/ Camphor 2% 240gms QTY: 3.00: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin; Topical Analgesics Page(s): 28-29; 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Salicylates, Topical.

**Decision rationale:** Regarding the capsaicin component, CA MTUS Chronic Pain Treatment Guidelines state that capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatment. The guidelines state there is no current indication that an increase over a 0.025% formulation would provide any further efficacy. ODG Pain Chapter issued an FDA safety warning which identifies rare cases of serious burns that have been reported to occur on the skin where over-the-counter (OTC) topical muscle and joint pain relievers were applied. These products contain the active ingredients menthol, methyl salicylate, or capsaicin. Regarding Tramadol, the topical formulation of Tramadol does not show consistent efficacy. In addition, there is little to no research as for the use of flurbiprofen in compounded products. In this case, the patient was prescribed Capsaicin .025%/ Flurbiprofen .15%/ Tramadol 15%/ Menthol 2%/ Camphor 2% 240gms cream since 03/05/2014. The patient complained of acid reflux symptoms associated with oral medications since 08/28/2013. The medical necessity for topical pain medication use has been established. However, the requested compound cream contained Flurbiprofen and tramadol, which are not recommended for topical use. Therefore, the request for Capsaicin .025%/ Flurbiprofen .15%/ Tramadol 15%/ Menthol 2%/ Camphor 2% 240gms cream QTY 3.00 is not medically necessary.

**Amitriptyline 4%/ Dextromethorphan 15%/ Flurbiprofen 20% 240gm QTY 3.00:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

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

**Decision rationale:** As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. Amitriptyline is a tricyclic antidepressant considered first-line agents, but there is no discussion regarding topical application of this drug. Guidelines provide no evidence-based recommendations regarding the use of topical dextromethorphan. In addition, there is little to no research as for the use of flurbiprofen in compounded products. Furthermore, the use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. In this case, the patient was prescribed Amitriptyline 4%/ Dextromethorphan 15%/ Flurbiprofen 20% 240gm since 03/05/2014. The patient complained of acid reflux symptoms associated with oral medications since 08/28/2013. The medical necessity for topical pain medication use has been established. However, the requested compound cream contained Flurbiprofen and amitriptyline, which are not recommended for topical use. Therefore, the

request for Amitriptyline 4%/ Dectromethorphan 15%/ Flurbiprofen 20% 240gm QTY 3.00 is not medically necessary.