

<b>Case Number:</b>	CM13-0035263		
<b>Date Assigned:</b>	12/13/2013	<b>Date of Injury:</b>	10/24/2003
<b>Decision Date:</b>	05/16/2014	<b>UR Denial Date:</b>	10/03/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/16/2013

### 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 Physical Medicine and Rehabilitation, and is licensed to practice in Texas. 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 injured worker is a 47-year-old male who reported an injury on 10/24/2003. The mechanism of injury was not provided. The injured worker's medical history included lactulose, Colace, hydrocodone, and omeprazole as of 2012. The documentation of 09/06/2013 revealed the injured worker had persistent low back pain of an 8/10 described as achy with pain radiating to the right lower extremity. The injured worker had intermittent sharp shooting and stabbing type of pain. The diagnosis was lumbago. The treatment plan included docusate sodium with 2 refills, hydrocodone, Lortab, ibuprofen, lactulose, Nexium, Lunesta, and to start tramadol cream 10% half a teaspoon to the painful region up to 2 times a day for pain, 1 jar with no refills.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**TRAMADOL CREAM 10% CREAM:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol, Topical Analgesics Page(s): 82, 111. Decision based on Non-MTUS Citation FDA.gov

**Decision rationale:** The MTUS Chronic Pain Guidelines indicate that topical analgesics are "largely experimental in use with few randomized controlled trials to determine efficacy or

safety ... are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed ... Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended ... Topical Salicylates are recommended." A thorough search of FDA.gov did not indicate there was a formulation of topical Tramadol that had been FDA approved. The approved form of Tramadol is for oral consumption, which is not recommended as a first line therapy. The clinical documentation submitted for review failed to indicate the injured worker had neuropathic pain. Additionally, it failed to indicate the injured worker had a trial and failure of antidepressants and anticonvulsants. Additionally, Tramadol is not FDA approved for topical application. The request as submitted failed to indicate the frequency and quantity of medication being requested. Given the above, the request for tramadol cream 10% cream is not medically necessary and appropriate.

**DOCUSATE SODIUM 250MG (COLACE) 250MG #60 TIMES 2 REFILLS:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 77.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 77.

**Decision rationale:** The MTUS Chronic Pain Guidelines recommend prophylactic treatment of constipation when initiating opioid therapy. The clinical documentation submitted for review indicated the injured worker had been utilizing the medication for greater than 1 year. There was a lack of documented efficacy. The injured worker was utilizing lactulose in addition to the requested medication. The request as submitted failed to indicate the frequency for the requested medication. There was a lack of documentation indicating the necessity for 2 refills. Given the above, the request for docusate sodium 250mg (Colace) 250mg #60 times 2 refills is not medically necessary.