

<b>Case Number:</b>	CM14-0111460		
<b>Date Assigned:</b>	09/19/2014	<b>Date of Injury:</b>	12/22/2003
<b>Decision Date:</b>	10/20/2014	<b>UR Denial Date:</b>	06/20/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/17/2014

### 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 Internal 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:

The patient is an injured worker who is status post lumbosacral spine surgery. The mechanism of injury was heavy lifting. Date of injury was 12-22-2003. The patient has complaints of low back pain associated with lower extremity radicular symptoms. The patient is status post L4-5 and L5-S1 fusion with disc replacement at L3-4 in 2011. Physical exam reveals lumbar tenderness. Colace, Dendracin Lotion, and Cialis were requested. Psychiatric report dated 2/14/14 documented that the patient reported having weak erections that is improved with Cialis. The patient's medication regimen included Hydrocodone and Docusate (Colace). The progress report dated 5/7/14 documented subjective complaints of low back pain. The patient underwent lumbar fusion at L4-L5 and LS-S1, with an artificial disc replacement at L3-L4 approximately three years ago. He continues to have moderate to severe low back pain with radiation to the lower extremities in the L3-L5 distributions. The patient has a history of impotency. Physical examination documented lumbosacral tenderness with flexion 70 degrees. Medications included Norco, Colace, and Cialis. Utilization review determination date was 6/20/14.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**DENDRACIN LOTION 120ML:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Capsaicin, topical NSAIDs (non-steroidal anti-inflammatory drugs) D.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address topical analgesics. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Capsaicin topical is only an option in patients who have not responded or are intolerant to other treatments. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The efficacy in clinical trials of topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be either not superior to placebo after two weeks, or with a diminishing effect after two weeks. For osteoarthritis of the knee, topical NSAID effect appeared to diminish over time. There are no long-term studies of their effectiveness or safety for chronic musculoskeletal pain. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Topical NSAIDs are not recommended for neuropathic pain as there is no evidence to support use. FDA package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile including liver and renal function tests. Routine blood pressure monitoring is recommended. It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time. Medical records do not present blood pressure measurements or laboratory test results, which are recommended for NSAID use per MTUS. Medical records indicate long-term NSAID use, which is not recommended by MTUS. Medical records do not document that the patient has not responded or is intolerant to other treatments, which is an MTUS requirement for the use of Capsaicin. Per MTUS, Capsaicin topical is only an option in patients who have not responded or are intolerant to other treatments. Per MTUS, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the use of topical Dendracin, which contains Methyl Salicylate, Capsaicin, and Menthol, is not supported by MTUS guidelines. Therefore, the request for DENDRACIN LOTION 120ML is not medically necessary.

**CIALIS 20MG #10:** Overturned

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation FDA Prescribing Information Cialis <http://www.drugs.com/pro/cialis.html>

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) does not address Cialis. FDA Prescribing Information reports that Cialis is indicated for erectile dysfunction. Medical records document the diagnosis of impotency. The patient reports erectile dysfunction that benefits from Cialis. Medical records and FDA guidelines support the use of Cialis. Therefore, the request for CIALIS 20MG #10 is medically necessary.

**COLACE 100MG #60:** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for use of opioids Page(s): Page 77.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines recommend prophylactic treatment of constipation for patients prescribed opioid medications. Medical records document the prescription of the opioid Hydrocodone. MTUS guidelines support the medical necessity of prophylactic treatment of constipation for patients prescribed opioid medications. The use Colace is supported. Therefore, the request for COLACE 100MG #60 is medically necessary.