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| <b>Case Number:</b>   | CM14-0193402 |                              |            |
| <b>Date Assigned:</b> | 12/01/2014   | <b>Date of Injury:</b>       | 06/13/2009 |
| <b>Decision Date:</b> | 01/15/2015   | <b>UR Denial Date:</b>       | 11/06/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 11/18/2014 |

### 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 Physical Medicine and Rehabilitation, has a subspecialty in Interventional Spine 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 a 47-year-old male with a date of injury of 06/13/2009. According to progress report 10/01/2014, the patient presents with continued right shoulder pain which is constant and aggravated by certain movements such as lifting the arm overhead. Patient rates pain as 5/10. Examination revealed stiffness and limited range of motion. Patient is weak in the internal and external rotations. X-rays of the right shoulder were taken on this date, which showed, "No increase of osteoarthritis." The listed diagnoses are: 1. Joint derangement, NEC-shoulder. 2. Dislocation of acromioclavicular-CL. 3. Joint pain-shoulder. 4. Arthritis-shoulder. 5. Sprain, rotator cuff. This is a request for Aleveer DIS 0.0375-5 #30. The utilization review denied the request on 11/06/2014. Treatment reports from 03/25/2014 through 10/01/2014 were reviewed and provide no discussion regarding this request.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Aleveer dis 0.0375-5 #30:** Upheld

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

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

Medical Treatment Guideline or Medical Evidence: [www.medlibrary.org/lib/rx/meds/aleveer-patch](http://www.medlibrary.org/lib/rx/meds/aleveer-patch)

**Decision rationale:** This patient presents with continued right shoulder pain. The current request is for Aleveer DIS 0.0375-5 #30. According to [www.medlibrary.org/lib/rx/meds/aleveer-patch](http://www.medlibrary.org/lib/rx/meds/aleveer-patch), Aleveer contains menthol 5% and capsaicin 0.0375%. The website indicates that "This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA." The MTUS Guidelines page 111 has the following regarding topical creams, "Topical analgesics are largely experimental and used with few randomized controlled trials to determine efficacy or safety." MTUS further states, "Any compounded product that contains at least one (or drug class) that is not recommended is not recommended." The MTUS Guidelines allows capsaicin for chronic pain condition such as fibromyalgia, osteoarthritis, and nonspecific low back pain. However, MTUS Guidelines consider doses that are higher than 0.025% to be experimental particularly at high doses. Aleveer contains 0.0375% of capsaicin, which is not supported by MTUS. In addition, this medication is not FDA approved to be safe and effective. The requested Aleveer is not medically necessary.