

|                       |              |                              |            |
|-----------------------|--------------|------------------------------|------------|
| <b>Case Number:</b>   | CM14-0077568 |                              |            |
| <b>Date Assigned:</b> | 07/18/2014   | <b>Date of Injury:</b>       | 08/31/2006 |
| <b>Decision Date:</b> | 08/25/2014   | <b>UR Denial Date:</b>       | 05/14/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 05/27/2014 |

### 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 Medicine 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 54 year old female injured on 8/31/06 due to an undisclosed mechanism of injury. Neither the specific injuries sustained nor the initial treatments rendered were discussed in the documents provided. Current diagnosis include tendonitis, shoulder disorders, shoulder and wrist sprain/strain. The clinical note dated 02/19/14 indicated the injured worker present complained of neck and right sided shoulder and wrist pain. The injured worker reported difficulty with activities of daily living and sleeping. Physical examination revealed spasm, tenderness, decreased range of motion, decreased sensation to the right C6 dermatome and guarding of the paravertebral muscles of the cervical spine. The request for compound lidocaine 6%, Ketoprofen 10%, gabapentin 10%, and Pentravan cream base 1 was non-certified on 05/14/14.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Compound Lidocaine 6%:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 71.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patch) Page(s): 56.

**Decision rationale:** As noted on page 56 of the Chronic Pain Medical Treatment Guidelines, the safety and efficacy of compounded medications has not been established through rigorous clinical trials. Lidoderm is recommended for a trial if there is evidence of localized pain that is consistent with a neuropathic etiology. There should be evidence of a trial of first-line neuropathy medications (tri-cyclic or SNRI anti-depressants or an anti-epileptic drug such as gabapentin or Lyrica). Lidocaine is not generally recommended for treatment of osteoarthritis or treatment of myofascial pain/trigger points. Therefore Compound Lidocaine 6% cannot be recommended as medically necessary as it does not meet established and accepted medical guidelines.

**Ketoprofen 10%:** Upheld

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

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

**Decision rationale:** As noted on page 111 of the Chronic Pain Medical Treatment Guidelines, the safety and efficacy of compounded medications has not been established through rigorous clinical trials. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is no indication in the documentation that these types of medications have been trialed and/or failed. Further, CAMTUS, Food and Drug Administration, and Official Disability Guidelines require that all components of a compounded topical medication be approved for transdermal use. Ketoprofen has not been approved for transdermal use. In addition, there is no evidence within the medical records submitted that substantiates the necessity of a transdermal versus oral route of administration. Therefore Ketoprofen 10% cannot be recommended as medically necessary as it does not meet established and accepted medical guidelines.

**Gabapentin 10%:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 71.

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

**Decision rationale:** As noted on page 111 of the Chronic Pain Medical Treatment Guidelines, the safety and efficacy of compounded medications has not been established through rigorous clinical trials. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is no indication in the documentation that these types of medications have been trialed and/or failed. Further, CAMTUS, Food and Drug Administration, and Official Disability Guidelines require that all components of a compounded topical medication be approved for transdermal use. Gabapentin has not been approved for transdermal use. In addition, there is no evidence within the medical records submitted that

substantiates the necessity of a transdermal versus oral route of administration. Therefore Gabapentin 10% cannot be recommended as medically necessary as it does not meet established and accepted medical guidelines.

**Penttravan cream base 1:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 71.

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

**Decision rationale:** As noted on page 111 of the Chronic Pain Medical Treatment Guidelines, the safety and efficacy of compounded medications has not been established through rigorous clinical trials. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is no indication in the documentation that these types of medications have been trialed and/or failed. Further, CAMTUS, Food and Drug Administration, and Official Disability Guidelines require that all components of a compounded topical medication be approved for transdermal use. Therefore Penttravan cream base 1 cannot be recommended as medically necessary as it does not meet established and accepted medical guidelines.