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| <b>Case Number:</b>   | CM13-0061002 |                              |            |
| <b>Date Assigned:</b> | 12/30/2013   | <b>Date of Injury:</b>       | 05/15/2013 |
| <b>Decision Date:</b> | 04/10/2014   | <b>UR Denial Date:</b>       | 11/18/2013 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 12/04/2013 |

### 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, has a subspecialty in Sports 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 patient is a 35-year-old male who reported injury on 05/15/2013. The patient's diagnosis was noted to be low back pain status post fracture of the coccyx. The mechanism of injury was noted to be the patient was climbing into end-dump trailer to sweep and he slipped and landed on his buttocks. The clinical documentation submitted for review indicated the physician was prescribing compounded Ketoprofen and compounded Cyclophene for pain. The physician indicated topical NSAIDs have been shown to be effective in the treatment of acute or chronic soft tissue and musculoskeletal pain, mild to moderate joint pain, and neuropathic pain. The request was made for compounded Ketoprofen and Cyclophene. The patient's diagnoses were noted to include low back pain status post fracture of the coccyx.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**COMPOUNDED KETOPROFEN 20% IN PLO GEL, 120 GRAMS:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Ketoprofen, Page(s): 111, 112.

**Decision rationale:** The California MTUS Chronic Pain Medical Treatment Guidelines indicates 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. Regarding the use of Ketoprofen: This agent is not currently FDA approved for a topical application. The MTUS guidelines do not recommend Ketoprofen. The clinical documentation submitted for review failed to indicate the patient had trialed and failed antidepressants and anticonvulsants. The patient was noted to be on the medication for more than one year. There was lack of documentation of functional improvement. The request for compound Ketoprofen 20% PLO gel 120 grams is not medically necessary and appropriate.

**COMPOUNDED CYCLOPHENE 5% IN PLO GEL, 120 GRAMS:** Upheld

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

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

**Decision rationale:** The California MTUS Chronic Pain Medical Treatment Guidelines indicates topical analgesics are experimental in use with few randomized controlled trials to determine efficacy or safety and 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. California MTUS Guidelines do not recommend the topical use of Cyclobenzaprine as topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. The clinical documentation submitted for review indicated the patient had been on the medication since 2012. There was lack of documentation indicating the patient had trialed and failed antidepressants and anticonvulsants. There was lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. The request for compounded Cyclophene 5% in PLO gel 120 grams is not medically necessary and appropriate.