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| <b>Case Number:</b>   | CM14-0102157 |                              |            |
| <b>Date Assigned:</b> | 07/30/2014   | <b>Date of Injury:</b>       | 05/23/2011 |
| <b>Decision Date:</b> | 10/17/2014   | <b>UR Denial Date:</b>       | 06/11/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 07/02/2014 |

### 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 Family 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:

This is a female patient who reported an industrial injury on 5/23/2011, over three (3) years ago, attributed to the performance of his usual and customary job tasks. The patient reported pain to the neck, low back, shoulder and was diagnosed with cervical disc herniation, lumbar disc herniation, and bilateral shoulder impingement syndrome. The objective findings on examination included tenderness to palpation along with diminished range of motion. The patient was prescribed topical NSAID gel, Keratek gel, and compounded topical creams, Flurbipro/Cyclobenzaprine/menthol C/Pentranan and Kera Tek Gel.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Compounded topical cream- Flurbipro/Cyclobenz/Menthol C/Pentranan 30 day supply QTY 180 Refills 0:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, Chronic Pain Treatment Guidelines anti-inflammatory medications, topical analgesics Page(s): 22, 67-68; 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), pain chapter-topical analgesic; compounded topical analgesics

**Decision rationale:** The prescription for compounded topical cream Flurbipro/Cyclobenz/Menthol C/Pentran 30-day supply QTY 180 Refills 0 is not medically necessary for the treatment of the patient for pain relief for the orthopedic diagnoses of the patient. There is no clinical documentation submitted to demonstrate the use of the topical gels for appropriate diagnoses or for the recommended limited periods of time. It is not clear that the topical compounded medications are medically necessary in addition to prescribed oral medications. There is no provided subjective/objective evidence that the patient has failed or not responded to other conventional and recommended forms of treatment for relief of the effects of the industrial injury. Only if the subjective/objective findings are consistent with the recommendations of the ODG, then topical use of topical preparations is only recommended for short-term use for specific orthopedic diagnoses. There is no provided rationale supported with objective evidence to support the prescription of the topical compounded cream. There is no documented efficacy of the prescribed topical compounded analgesics with any assessment of functional improvement. The patient is stated to have reduced pain with the topical creams, however, there is no functional assessment, and no quantitative decrease in pain documented. The use of topical NSAIDs is documented to have efficacy for only 2-4 weeks subsequent to injury and thereafter is not demonstrated to be as effective as oral NSAIDs. There is less ability to control serum levels and dosing with the topicals. The patient is not demonstrated to have any GI issue at all with NSAIDs. There is no demonstrated medical necessity for topical NSAIDs for chronic pain for a prolonged period of time. The request for the topical compounded topical cream Flurbipro/Cyclobenz/Menthol C/Pentran 30-day supply QTY 180 Refills 0 is not medically necessary for the treatment of the patient for the diagnosis of the chronic pain. The use of the topical gels/creams does not provide the appropriate therapeutic serum levels of medications due to the inaccurate dosing performed by rubbing variable amounts of gels on areas that are not precise. The volume applied and the times per day that the gels are applied are variable and do not provide consistent serum levels consistent with effective treatment. There is no medical necessity for the addition of gels to the oral medications in the same drug classes. There is no demonstrated evidence that the topicals are more effective than generic oral medications. The use of compounded topical cream Flurbipro/Cyclobenz/Menthol C/Pentran 30-day supply QTY 180 Refills 0 is not supported by the applicable evidence-based guidelines as cited above. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or demonstrated to be appropriate. There is no documented objective evidence that the patient requires both the oral medications

**Kera Tek Gel 30 Day supply QTY 113 Refills 0:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 112, 113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics; NSAIDs pages Page(s): 111-113; 22, 67-68, 71. Decision based on Non-MTUS Citation ACOEM Practice Guidelines, Chapter 6 pages 114-15, Official Disability Guidelines (ODG), Pain Chapter topical analgesics; NSAIDs

**Decision rationale:** The prescription for Kera-Tek analgesic gel 30-day supply quantity 113 refills 0 is not medically necessary for the treatment of the patient for pain relief for the

orthopedic diagnoses of the patient as opposed to the readily available salicylate preparations available over-the-counter. It is not clear that the topical salicylate gel is medically necessary in addition to prescribed oral medications. There is no provided subjective/objective evidence that the patient has failed or not responded to other conventional and recommended forms of treatment for relief of the effects of the industrial injury. Only if the subjective/objective findings are consistent with the recommendations of the ODG, then topical use of topical preparations is only recommended for short-term use for specific orthopedic diagnoses. The request for Kera-Tek analgesic gel 30-day supply quantity 113 refills 0 is not medically necessary for the treatment of the patient for the diagnosis of lower back pain. There are many alternatives available OTC for the prescribed topical analgesics or topical salicylates. The use of the topical creams or gels do not provide the appropriate therapeutic serum levels of medications due to the inaccurate dosing performed by rubbing variable amounts of creams on areas that are not precise. The volume applied and the times per day that the creams are applied are variable and do not provide consistent serum levels consistent with effective treatment. There is no medical necessity for the addition of creams to the oral medications in the same drug classes. There is no demonstrated evidence that the topicals are more effective than generic oral medications. The use of Kera-Tek analgesic gel 30-day supply quantity 113 refills 0 not supported by the applicable ODG guidelines as cited below. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or demonstrated to be appropriate. There is no documented objective evidence that the patient requires both the oral medications and the topical compounded medication for the treatment of the industrial injury. The prescription for Kera-Tek analgesic gel 30-day supply quantity 113 refills 0 is not medically necessary for the treatment of the patient's pain complaints. The prescription of Kera-Tek analgesic gel 30-day supply quantity 113 refills 0 is not recommended by the CA MTUS and the Official Disability Guidelines. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or appropriate - noting the specific comment, "There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder." The objective findings in the clinical documentation provided do not support the continued prescription for the treatment of chronic pain over the available OTC topical salicylate preparations.