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| <b>Case Number:</b>   | CM14-0119920 |                              |            |
| <b>Date Assigned:</b> | 08/06/2014   | <b>Date of Injury:</b>       | 02/27/2009 |
| <b>Decision Date:</b> | 09/29/2014   | <b>UR Denial Date:</b>       | 07/01/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 07/30/2014 |

### 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 Occupational 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:

According to the records made available for review, this is a 45-year-old male. At the time (6/19/14) of request for authorization for Topical cream (Flurbiprofen 20%/Tramadol 20% in mediderm base) 210gms, Topical Cream (Gabapentin 10%/Amitriptyline 10%/Dextromethorphan 10% in Mediderm base) 210gms, and Theratramadol -90 (Copak:Theramine #90/Tramadol 50 mg #60), there is documentation of subjective (epigastric abdominal pain, worsening orthopedic complaints, neck pain with headaches rated at 5 out of 10, and low back pain radiating down both legs) and objective (no pertinent findings) findings, current diagnoses (abdominal pain, acid reflux secondary to NSAIDs, cephalgia, and orthopedic complaints), and treatment to date (medications (ongoing therapy with Medrox patches, Dexilant, topical Flurbiprofen/Tramadol, and Tramadol). Regarding Topical cream (Flurbiprofen 20%/Tramadol 20% in mediderm base) 210gms, there is no documentation that trials of antidepressants and anticonvulsants have failed, and functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of use of Topical Flurbiprofen/Tramadol.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Topical cream (Flurbiprofen 20%/Tramadol 20% in mediderm base)210 gms:** Upheld

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

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

**Decision rationale:** The Expert Reviewer based his/her decision on the MTUS Chronic Pain Medical Treatment Guidelines, Topical Analgesics, page 111 and on the Non-MTUS Other Medical Treatment Guideline or Medical Evidence: Title 8, California Code of Regulations. The Expert Reviewer's decision rationale: MTUS Chronic Pain Medical Treatment Guidelines identifies that "topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." MTUS-Definitions identifies that "any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services." Within the medical information available for review, there is documentation of neuropathic pain. However, there is no documentation that trials of antidepressants and anticonvulsants have failed. In addition, given documentation of ongoing treatment with topical Flurbiprofen/Tramadol, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of use of Topical Flurbiprofen/Tramadol. Therefore, based on guidelines and a review of the evidence, the request for Topical cream (Flurbiprofen 20%/Tramadol 20% in mediderm base) 210gms is not medically necessary.

**Topical Cream ( gabapentin 10%/Amitriptyline 10%/Dextromethorphan 10% in Mediderm base)210 gms: Upheld**

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

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

**Decision rationale:** The Expert Reviewer based his/her decision on the MTUS Chronic Pain Medical Treatment Guidelines, Topical Analgesics, page 111-113. The Expert Reviewer's decision rationale: MTUS Chronic Pain Medical Treatment Guidelines identifies that "many agents are compounded as monotherapy or in combination for pain control; that ketoprofen, Lidocaine (in creams, lotion or gels), capsaicin in a 0.0375% formulation, baclofen and other muscle relaxants, and gabapentin and other Antiepilepsy drugs are not recommended for topical applications; and that any compounded product that contains at least one drug (or drug class) that is not recommended, is not recommended." Within the medical information available for review, there is documentation of diagnoses of status post revision lumbar fusion, status post previous lumbar fusion, lumbar discogenic disease, possible early sacroiliac joint dysfunction, cervical strain, and cervical spine degenerative disc disease. However, the requested topical compounded medication consists of at least one drug class (muscle relaxants) that is not recommended. Therefore, based on guidelines and a review of the evidence, the request for Topical Cream

(Gabapentin 10%/Amitriptyline 10%/Dextromethorphan 10% in Mediderm base) 210gms is not medically necessary.

**Theratramadol -90 ( Copak:Theramine #90/Tramadol 50 mg #60):** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG- 11 th edition web 2013 Pain, Medical food.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Co-pack drugs; Theramine.

**Decision rationale:** The Expert Reviewer based his/her decision on the Non-MTUS Official Disability Guidelines (ODG) Pain, Co-pack drugs; Theramine. The Expert Reviewer's decision rationale:MTUS does not address the issue. ODG identifies that "Co-packs are convenience packaging of a medical food product and a generic drug into a single package that requires a prescription." In addition, ODG identifies that Theramine is a medical food and is not recommended. Therefore, based on guidelines and a review of the evidence, the request for Theratramadol -90 (Copak:Theramine #90/Tramadol 50 mg #60) is not medically necessary.