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| <b>Case Number:</b>   | CM15-0199179 |                              |            |
| <b>Date Assigned:</b> | 10/14/2015   | <b>Date of Injury:</b>       | 10/23/2006 |
| <b>Decision Date:</b> | 11/20/2015   | <b>UR Denial Date:</b>       | 10/01/2015 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 10/09/2015 |

### 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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: Montana, Oregon, Idaho

Certification(s)/Specialty: Orthopedic Surgery

### 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 44 year old male, who sustained an industrial injury on 10-23-2006. The injured worker is currently permanent, stationary, and able to work part time. Medical records indicated that the injured worker is undergoing treatment for cervical disc bulging with mild neural foraminal stenosis and radicular pain, lumbar disc bulging with radicular pain, and reactive depression with chronic pain syndrome. Treatment and diagnostics to date has included medications. Recent medications have included Motrin, Topamax, Fexmid (since at least 06-29-2015), Cymbalta, Protonix, Terocin lotion (since at least 09-22-2015), and Medrol patches (since at least 06-29-2015). After review of progress notes dated 06-29-2015 and 09-22-2015, the injured worker reported back pain. Objective findings included pain with cervical and lumbar range of motion and tenderness along her bilateral sacroiliac joint. The treating physician noted that the injured worker will be using the Medrox patches and Terocin lotion to her spine. The request for authorization dated 09-22-2015 requested Fexmid 7.5mg every day #60, Cymbalta, Protonix, Medrox patches (20% Methyl Salicylate, 5% Menthol, 0.0375% Capsaicin) x 6 boxes, and Terocin lotion (20% Methyl Salicylate, 10% Menthol, 0.025% Capsaicin, 2.5% Lidocaine) x 2 bottles. The Utilization Review with a decision date of 10-01-2015 denied the request for Fexmid 7.5mg Quantity: 60, Medrox Patches (20% Methyl Salicylate, 5% Menthol, 0.0375% Capsaicin) (boxes) Quantity: 2, and Terocin Lotion (20% Methyl Salicylate, 10% Menthol, 0.025% Capsaicin, 2.5% Lidocaine) (boxes) Quantity: 2.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Fexmid 7.5 MG Qty 60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

**Decision rationale:** CA MTUS Chronic Pain Medical Treatment Guidelines, pages 64-65, reports that muscle relaxants are recommended to decrease muscle spasm in condition such as low back pain although it appears that these medications are often used for the treatment of musculoskeletal conditions whether spasm is present or not. The mechanism of action for most of these agents is not known. CA MTUS Chronic Pain Medical Treatment Guidelines, page 41 and 42, report that Cyclobenzaprine/Fexmid, is recommended as an option, using a short course of therapy. See Medications for chronic pain for other preferred options. Cyclobenzaprine (Fexmid) is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. (Browning, 2001) Treatment should be brief. This medication is not recommended to be used for longer than 2-3 weeks. There is also a post-op use. The addition of cyclobenzaprine to other agents is not recommended. In this case, the records indicate the injured worker has been taking fexmid since at least 6/29/15. This duration exceeds the duration of treatment recommended by the guidelines and is therefore not medically necessary.

**Medrox Patches (20 Percent Methyl Salicylate, 5 Percent Menthol, .0375 Percent Capsaicin) (Boxes) Qty 2:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** Per the CA MTUS regarding topical analgesics, Chronic Pain Medical Treatment Guidelines, Topical analgesics, page 111-112 "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, the determination is for non-certification. Methyl Salicylate is the only ingredient which is recommended by the guidelines and has evidence to support its use in the treatment of chronic pain. The remainder of ingredients in the requested compound has no evidence to support their use. Therefore, the requested compound is not medically necessary.

**Terocin Lotion (20 Percent Methyl Salicylate, 10 Percent Menthol, .025 Percent Capsaicin, 2.5 Percent Lidocaine) Qty 2: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** Per the CA MTUS regarding topical analgesics, Chronic Pain Medical Treatment Guidelines, Topical analgesics, page 111-112 "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, the determination is for non-certification. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. As this request contains lidocaine as an ingredient in the compounded medication, and it is not recommended by the guidelines in lotion form, the request is not medically necessary.