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| Case Number: | CM15-0215328 | | |
| Date Assigned: | 11/05/2015 | Date of Injury: | 02/28/2015 |
| Decision Date: | 12/18/2015 | UR Denial Date: | 10/16/2015 |
| Priority: | Standard | Application Received: | 11/02/2015 |

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: California

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

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 50-year-old female with a date of industrial injury 2-28-2015. The medical records indicated the injured worker (IW) was treated for lumbar spine musculoligamentous strain-sprain with radiculitis, rule out lumbar spine discogenic disease; right shoulder strain-sprain, tendinosis; rule out right shoulder rotator cuff tear; right hip strain-sprain, trochanteric bursitis; right knee strain-sprain, rule out internal derangement; left ankle strain-sprain; and sleep disturbance secondary to pain. In the progress notes (9-18-15), the IW reported pain in the lower back, right hip and right knee rated 8 out of 10, which was improved since her last visit from 8 to 9 out of 10. The right shoulder and right ankle were both asymptomatic. On examination (9-18-15 notes), the tenderness in the lumbar paraspinal muscles, right hip, right knee and left ankle was unchanged since her last exam and the tenderness in the right shoulder was decreased. Her neurocirculatory exam was unchanged. Treatments included physical therapy and lumbar epidural steroid injection. The IW was temporarily totally disabled. The treatment plan included chiropractic treatment, Tramadol, Theramine and topical analgesics; extracorporeal shockwave therapy and urine drug screen. A Request for Authorization was received for Theramine #90, Flurbi (NAP) cream-LA (Flurbiprofen 20%, Lidocaine 5% and Amitriptyline 5%) 180gm and Gabacyclotram (gabapentin 10%, Cyclobenzaprine 6% and Tramadol 10%) 180gm. The Utilization Review on 10-16-15 non-certified the request for Theramine #90, Flurbi (NAP) cream-LA (Flurbiprofen 20%, Lidocaine 5% and Amitriptyline 5%) 180gm and Gabacyclotram (gabapentin 10%, Cyclobenzaprine 6% and Tramadol 10%) 180gm.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine #90: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Theramine.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter/Theramine Section.

Decision rationale: MTUS guidelines do not address the use of Theramine; therefore, alternative guidelines were consulted. Per the ODG, Theramine is not recommended. Theramine is not recommended for the treatment of chronic pain. Theramine is a medical food that contains 5-hydroxytryptophan 95%, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine, gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa (theobromine 6%). It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. Theramine is not supported by the guidelines. The request for Theramine #90 is not medically necessary.

Flurbi (NAP) cream-LA (Flurbiprofen 20%/ Lidocaine 5%/ Amitriptyline 5%) 180gm: 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): Amitriptyline, NSAIDs (non-steroidal anti-inflammatory drugs), Topical Analgesics.

Decision rationale: The MTUS Guidelines recommend the use of topical analgesics as an option for the treatment of chronic pain, however, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. Topical NSAIDs have been shown to be superior to placebo for 4-12 weeks for osteoarthritis of the knee. Topical flurbiprofen is not an FDA approved formulation. Topical lidocaine is used primarily for neuropathic pain when trials of antidepressants and anticonvulsants have failed. 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. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. There is no clear evidence in the clinical reports that this injured worker has neuropathic pain that has failed treatment with trials of antidepressants and anticonvulsants. Amitriptyline is a tricyclic antidepressant that shares some properties of muscle relaxants. The MTUS Guidelines and ODG do not address the use of Amitriptyline or other

antidepressants as topical agents for pain; however, the MTUS Guidelines specifically reports that there is no evidence to support the use of topical formulations of muscle relaxants. As at least one of the medications in the requested compounded medication is not recommended by the guidelines, the request for Flurbi (NAP) cream-LA (Flurbiprofen 20%/ Lidocaine 5%/ Amitriptyline 5%) 180gm is not medically necessary.

Gabacyclotram (Gabapentin 105/ Cyclobenzaprine 6%/ Tramadol 10%) 180gm: 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): Cyclobenzaprine (Flexeril), Muscle relaxants (for pain), Topical Analgesics.

Decision rationale: The MTUS Guidelines recommend the use of topical analgesics as an option for the treatment of chronic pain, however, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. The MTUS Guidelines do not recommend the use of topical gabapentin, as there is no peer-reviewed literature to support use. The MTUS Guidelines state that there is no evidence for use of muscle relaxants such as cyclobenzaprine as a topical product. The MTUS Guidelines state that tramadol is not recommended as a first-line oral analgesic. The MTUS Guidelines do not specifically address the use of topical tramadol. As at least one of the medications in the requested compounded medication is not recommended by the guidelines, the request for Gabacyclotram (Gabapentin 105/ Cyclobenzaprine 6%/ Tramadol 10%) 180gm is not medically necessary.