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| Case Number: | CM15-0035792 | | |
| Date Assigned: | 03/04/2015 | Date of Injury: | 02/04/2003 |
| Decision Date: | 04/14/2015 | UR Denial Date: | 01/29/2015 |
| Priority: | Standard | Application Received: | 02/25/2015 |

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, Arizona

Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 55-year-old male who reported an injury on 02/04/2003. The mechanism of injury was not provided. The injured worker was utilizing topical medications. The documentation of 01/09/2015 revealed the injured worker had complaints of constant and moderate pain to moderately severe neck pain rated 5/10 with radiation to the bilateral upper extremities, with associated numbness and tingling. The physical examination revealed a positive straight leg raise bilaterally. There was motor strength weakness in the bilateral extensor hallucis longus motor groups at 4/5. The sensory examination revealed a deficit over L5 and S1 dermatomes. The diagnoses included spinal stenosis at L4-5 lateral recess, cervical spine and thoracic spine sprain/strain rule out herniated nucleus pulposus. The treatment plan included a home exercise program and topical medications which provided the injured worker with temporary relief. The injured worker was unable to utilize oral medications due to stomach complaints.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbiprofen 20% cream 120gm, to be applied on the affected area two to three times (2-3) a day: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen; Topical analgesics Page(s): 72; 111.

Decision rationale: The California Medical Treatment Utilization Schedule guidelines indicate that topical analgesics are 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. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. Flurbiprofen is classified as a non-steroidal anti-inflammatory agent. This agent is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institute of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration. The clinical documentation submitted for review failed to provide documentation of exceptional factors to warrant nonadherence to guideline recommendations. There was a lack of documentation indicating a necessity for 2 topical creams containing flurbiprofen. There was a lack of documentation indicating a necessity for noncompliance to FDA regulations. The documentation failed to include exceptional factors to warrant nonadherence. Given the above, the request for flurbiprofen 20% cream 120gm, to be applied on the affected area two to three times (2-3) a day is not medically necessary.

Ketoprofen 20% Ketamine 10% cream 120gm to be applied to the affected area two to three (2-3) times a day: 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; Ketoprofen; Ketamine Page(s): 111; 112; 113.

Decision rationale: The California Medical Treatment Utilization Schedule guidelines indicate that 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. Ketoprofen is not currently FDA approved for a topical application. The compound also included topical Ketamine which is under study and is only recommended in treatment of neuropathic pain which is refractory to all primary and secondary treatment. The guidelines do not recommend Ketoprofen and as such the use of the compound would not be supported. The clinical documentation submitted for review failed to provide documentation of exceptional factors. There was a lack of documentation indicating the injured worker's pain was refractory to all primary and secondary

treatments. There was a lack of documentation of trial and failure of antidepressants and anticonvulsants. Given the above, the request for ketoprofen 20% ketamine 10% cream 120gm to be applied to the affected area two to three (2-3) times a day is not medically necessary.

Gabapentin 10% Cyclobenzaprine 10%/Capsaicin 0.037% cream 120gm to be applied on the affected area two to three (2-3) times a day: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine; Topical Analgesics; Gabapentin; Topical Capsaicin Page(s): 41; 111; 113; 28.

Decision rationale: The California Medical Treatment Utilization Schedule guidelines indicates that 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." Gabapentin is not recommended. There is no peer-reviewed literature to support use. Other anti-epilepsy drugs: There is no evidence for use of any other anti-epilepsy drug as a topical product "do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product." The addition of cyclobenzaprine to other agents is not recommended. Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. There was a lack of documentation of trial and failure of antidepressants and anticonvulsants. The clinical documentation submitted for review failed to provide documentation of exceptional factors. Given the above, the request for Gabapentin 10% Cyclobenzaprine 10%/Capsaicin 0.037% cream 120gm to be applied on the affected area two to three (2-3) times a day is not medically necessary.