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| Case Number: | CM14-0063860 | | |
| Date Assigned: | 07/11/2014 | Date of Injury: | 08/11/2011 |
| Decision Date: | 09/16/2014 | UR Denial Date: | 04/15/2014 |
| Priority: | Standard | Application Received: | 05/06/2014 |

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:

The patient is a 66-year-old male who has submitted a claim for lumbar spine and strain, hypertrophic facet disease, left lower extremity radiculopathy, left knee sprain and strain with possible internal derangement, right elbow epicondylitis, and cervical spine musculoligamentous injury associated with an industrial injury date of August 11, 2011. Medical records from May 3, 2012 up to March 16, 2014 were reviewed showing continued pain and stiffness of his lumbar spine with radiations to left leg and buttock. Patient also complained of ongoing painful left knee. Lumbar spine examination revealed paraspinal tenderness with spasticity. Range of motion remains limited with positive straight leg raises on the left. MRI was reviewed showing hypertrophic facet disease at the bilateral L5-S1 level. Treatment to date has included Flurbi cream and Gabacyclotram cream, Norco, Flexeril, Naproxen, and Tramadol. This request is not supported by the CA-MTUS for topical compounded analgesics since safety and efficacy has not been proven. There has been no failed trials of first-line medications for the patient's condition.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective request (DOS: 3/5/14) for compound:
Flurbiprofen/Amitriptyline/Verapamil/Tetracaine: 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 based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: FDA, Tetracaine cream.

Decision rationale: Pages 111-113 of the CA MTUS Chronic Pain Medical Treatment Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of many these agents. In addition, there is little to no research as for the use of flurbiprofen in compounded products. Amitriptyline is a tricyclic antidepressant considered first-line agents, but there is no discussion regarding topical application of this drug. The FDA has approved lidocaine/tetracaine cream for local analgesia, however, only for superficial aesthetic procedures. The guidelines do not address verapamil in topical formulation. In this case, medical records reviewed did not show failure of oral formulations. Furthermore, the patient is currently taking naproxen, and there is no discussion regarding the need for combined use of oral and topical analgesics. Moreover, the requested medication contains flurbiprofen and amitriptyline which are not recommended for topical use. Guidelines state that any compounded product that contains a drug class that is not recommended is not recommended. Therefore, the Retrospective request (dos: 3/5/14) for compound flurbiprofen/amitriptyline/verapamil/tetracaine was not medically necessary.

**Retrospective request (DOS: 3/5/14) for compound:
Gabapentin/Cyclobenzaprine/Tramadol/Flurbiprofen:** 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: Pages 111-113 of the CA MTUS Chronic Pain Medical Treatment Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of many these agents. Regarding the tramadol component, the topical formulation of tramadol does not show consistent efficacy. Regarding the gabapentin component, guidelines do not recommend gabapentin because it does not show consistent efficacy. Cyclobenzaprine is not recommended for use as a topical analgesic. In addition, there is little to no research as for the use of flurbiprofen in compounded products. In this case, medical records reviewed did not show failure of oral formulations. Moreover, Flurbiprofen, cyclobenzaprine, tramadol, and gabapentin are not recommended for topical use. Guidelines state that any compounded product that contains a drug class that is not recommended is not recommended. Furthermore, the patient is currently taking naproxen and Flexeril. There is no discussion regarding the need for the combined use of oral and topical analgesics and muscle relaxant. Therefore, the Retrospective request (dos: 3/5/14) for compound gabapentin/cyclobenzaprine/ tramadol/ flurbiprofen was not medically necessary.

