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| Case Number: | CM15-0040485 | | |
| Date Assigned: | 03/10/2015 | Date of Injury: | 11/21/2008 |
| Decision Date: | 05/08/2015 | UR Denial Date: | 02/11/2015 |
| Priority: | Standard | Application Received: | 03/03/2015 |

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, Washington

Certification(s)/Specialty: Physical Medicine & Rehabilitation, Pain Management

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 female who reported an injury on 11/21/2008. The mechanism of injury was not provided. The diagnoses included chronic pain syndrome and DDD of the lumbar and cervical spine. The documentation indicated the requested medication was for neuropathic pain with a large inflammatory component. The documentation of 01/20/2015 revealed the injured worker had a complaint of drug dependency. The injured worker was in the office for follow-up maintenance and surveillance during Suboxone therapy. The injured worker was noted to have a constant burning pain in her low back and right buttocks. The injured worker indicated it was improving with conservative therapy. The injured worker was noted to be prescribed 2 films/tabs of 8 mg/2 mg Suboxone per day that is being taken every morning and the injured worker is utilizing Celebrex 200 mg daily with food. The injured worker denied cravings during the last month and said there had been no aberrant use of medications other than those prescribed by a physician. The medications were noted to be counted and the pill count was accurate. The urine specimen was positive with only prescribed medications. The injured worker was noted to undergo surgical interventions for the lumbar spine. The injured worker's current medications included tizanidine 4 mg, Flector 1.3% patches, Suboxone 8 mg to 2 mg sublingual film, and Celebrex 200 mg. The injured worker was noted to have back pain. The diagnoses included failed back syndrome lumbar, opioid type dependence, continuous pattern of use, sacroiliitis, radiculopathy, degenerative disc disease of the lumbar spine. The treatment plan included topical ointment, Celebrex, and Suboxone.

IMR ISSUES, DECISIONS AND RATIONALES

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

Compound Tramadol 3%, Bupivacaine 1%, Diclofenac 3%, Doxepin 3%, Gabapentin 6%, Orphenadrine 5%, Pentoxifyline 3% #120 with 1 refill: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics, Tramadol, Bupivacaine, Diclofenac, Topical Gabapentin, Topical Muscle Relaxants Page(s): 111, 82, 55, 112, 113, 113. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Skolnick P (1999) Antidepressants for the new millennium. Eur J Pharmacol 375:31-40.
<http://www.drugs.com/search.php?searchterm=Pentoxifyline&a=1&m=pentoxyl>.

Decision rationale: The California Medical Treatment Utilization Schedule guidelines indicate that topical analgesics are experimental and are in use with few randomized controlled trials to determine efficacy or safety. They 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 "A thorough search of FDA.gov, did not indicate there was a formulation of topical Tramadol that had been FDA approved. The approved form of Tramadol is for oral consumption, which is not recommended as a first line therapy." Bupivacaine has been recommended as an alternative to clonidine, however a search of FDA guidelines indicate that Bupivacaine is approved for injection. The guidelines indicate that topical NSAIDs are recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Peer reviewed literature states that while local peripheral administration of antidepressants has been demonstrated to produce analgesia in the formalin model of tonic pain; a number of actions, to include inhibition of noradrenaline (NA) and 5-HT reuptake, inhibition of NMDA, nicotinic, histamine, and 5-HT receptors, and block of ion channels and even combinations of these actions, may contribute to the local peripheral efficacy of antidepressant; therefore the contribution of these actions to analgesia by antidepressants, following either systemic or local administration, remains to be determined. Topical Gabapentin is not recommended as there is no peer reviewed literature to support its use. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. Per Drug.com, "Pentoxifylline is used to improve blood flow and reduce certain symptoms of a condition called intermittent claudication." The clinical documentation submitted for review failed to provide documentation of a trial and failure of antidepressants and anticonvulsants. Multiple components of the medication are not recommended and as such, this medication would not be recommended. There was a lack of documentation indicating a necessity for multiple pain medications. The rationale for use was not provided. The request as submitted failed to indicate the frequency and the body part to be treated. There was a lack of documentation indicating a necessity for 1 refill without re-evaluation. Given the above, the request for compound tramadol 3%, bupivacaine 1%, diclofenac 3%, doxepin 3%, gabapentin 6%, orphenadrine 5%, pentoxifyline 3% #120 with 1 refill is not medically necessary. Additionally, there was a lack of documentation indicating a necessity for pentoxifylline. Therefore, the request is not medically necessary.