

| | | | |
|-----------------------|--------------|------------------------------|------------|
| Case Number: | CM15-0028652 | | |
| Date Assigned: | 02/20/2015 | Date of Injury: | 11/01/2012 |
| Decision Date: | 03/31/2015 | UR Denial Date: | 01/13/2015 |
| Priority: | Standard | Application Received: | 02/17/2015 |

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:

The injured worker is a 52 year old female, who sustained an industrial injury reported on 11/1/2012. She has reported cumulative trauma to the back and elbow. The history noted work place injuries to her lumbar spine, right foot and heel - versus ankle sprain, headaches, neural, and gastroesophageal reflux from medication, going back to 11/1/2012. The diagnoses were noted to have included lumbosacral neuritis, disc degeneration, and spondylosis; lumbar disc protrusion with moderate foraminal narrowing; left lateral epicondylitis and lateral left elbow carpal tunnel syndrome with ulnar neuritis. Treatments to date have included consultations; diagnostic imaging studies; cubital tunnel redo surgery with ulnar transposition (10/27/14); activity restrictions; and medication management. No electrodiagnostic studies were noted. The work status classification for this injured worker (IW) was noted to be off work. The 12/4/2014 SOAP notes show subjective complaints for frequent, bilateral lumbosacral pain and frequent right sciatica pain for which electro-acupuncture and infrared treatments were provided. The 1/9/2015 therapy notes state the left elbow is doing better but is still sore and swells, and was assessed at achieving moderate progress to 100% progress on established goals. On 1/13/2015, Utilization Review (UR) non-certified, for medical necessity, the request, made on 11/24/2014, for a compounded topical cream with: Baclofen USP 4.8 gm, Bupivacaine HCL USP monohydrate 2.4gm, Cyclobenzaprine HCL USP 4.8gm, Dimethyl Sulfoxide USP 9.6gm, Gabapentin USP 14.4gm, Orphenadrine Citrate USP 12gm, Pentoxifylline USP 7.2 gm, Ethoxy Diglycol Reagent 24ml; and Sterabase 160.8gm. The Medical Treatment Utilization Schedule -

web edition, the American College of Occupational and Environmental Medicine Guidelines, and the Official Disability Guidelines - web edition, were cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

Compound topical medication: baclofen 4.8grams, bupivacaine 2.4 gm, cyclobenzaprine 4.8 gm, dimethyl sulfoxide 9.6 gm, gabapentin 14.4 gm, orphenadrine citrate 12 gm, pentoxifylline 7.2 gm, ethoxy diglycol reagent 24ml sterabase 160.8 gm.: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics; Muscle Relaxants; Antiepileptic Drugs Page(s): 16-9, 41-2, 49, 63-6, 111-13.

Decision rationale: Baclofen/Bupivacaine/Cyclobenzaprine/Dimethyl Sulfoxide/Gabapentin/Orphenadrine/Pentoxifylline/Ethoxy Diglycol/Stearate Cream is a combination product formulated for topical use. It is made up of baclofen (a antispasticity agent), bupivacaine (an anesthetic), cyclobenzaprine (a muscle relaxant), dimethyl sulfoxide (a topical analgesic), gabapentin (an anticonvulsant), orphenadrine (a muscle relaxant), ethoxy diglycol reagent (a solvent), and sterabase (a moisturizing cream). The use of topical agents to control pain is considered by the MTUS to be an option in therapy of chronic pain although it is considered largely experimental, as there is little to no research to support their use. Baclofen is indicated for oral use to treat muscle spasms caused by multiple sclerosis or spinal cord injuries but the MTUS does not recommend its use as a topical agent. Topical bupivacaine is not specifically mentioned by the MTUS but it does note use of topical local anesthetics is effective for local pain relief but are not recommended for treatment of chronic pain as more research is needed to prove effectiveness and safety. The MTUS does not address the topical use of cyclobenzaprine or orphenadrine but notes that when used systemically, either of these medications' use should be brief (no more than 2-3 weeks) and not combined with other medications. Gabapentin is an effective oral medication in controlling neuropathic pain, but the MTUS does not recommend its use topically. Pentoxifylline is a methylxanthine derivative with a variety of anti-inflammatory effects currently approved by the FDA only for the treatment of intermittent claudication. Dimethyl sulfoxide (DMSO) is a topical analgesic with limited effectiveness in lessening pain from chronic regional pain syndrome. Ethoxy diglycol reagent and sterabase use are not addressed by the MTUS. It is important to note the MTUS states: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Since baclofen, bupivacaine and gabapentin are not recommended for topical use, this product is not recommended. Medical necessity for use of this preparation has not been established.