

Case Number:	CM15-0173294		
Date Assigned:	09/15/2015	Date of Injury:	03/18/2013
Decision Date:	11/06/2015	UR Denial Date:	08/26/2015
Priority:	Standard	Application Received:	09/02/2015

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:

The injured worker (IW) is a 37 year old female who sustained an industrial injury on 03-18-2013. The injured worker was diagnosed as having Headaches, Cervical Spine Strain-Sprain, Cervical Radiculopathy, Thoracic Spine Strain-Sprain, Lumbar Spine Strain-Sprain, Lumbar Radiculopathy, Right Shoulder Osteoarthritis, Status post Right Shoulder Surgery (no date given) , and Right wrist Strain-Sprain. Treatment to date has included medications and diagnostic MRI. In the exam of 07-29-2015, the injured worker complains of constant headaches, neck pain radiating to the upper extremities with numbness and tingling, mid back pain, constant right shoulder pain , and constant right wrist pain with numbness and tingling, each of which she rates at a pain level of 7 on a scale of 0-10. She also complains of constant low back pain radiating to the bilateral lower extremities with numbness and tingling that she rates as a 6 on a scale of 0-10. MRI of the right wrist with flexion and extension (12-21-2013) was noted to show a ganglion cyst at the dorsal aspect of the radiocarpal joint, a small subchondral cyst at the head of the 3rd metacarpal and triquetral. A MRI of the right elbow was unremarkable (09-28-2013), and a MRI of the right hand was unremarkable (12-20-2013). Objectively, the cervical range of motion on is flexion 40 degrees, extension 45 degrees, right rotation 65 degrees, left rotation 65 degrees, right lateral flexion 25 degrees, left lateral flexion 30 degrees. She has tenderness to palpation along the cervical spine and along the trapezius muscles bilaterally with palpable spasms. Spurling's test is negative bilaterally. The right shoulder range of motion is flexion 140 degrees, extension 25 degrees, abduction 140 degrees, adduction 40 degrees, internal rotation 60 degrees, external. The right wrist range of motion is

flexion 50 degrees, extension 50 degrees, radial deviation to 10 degrees, ulnar deviation 20 degrees, and Phalen's test is positive on the left. The worker was given prescriptions for compounded topical medications, and vitamins and food supplements. She was recommended to continue with a home exercise program. A request for authorization was submitted for: 1. Ibuprofen 600mg #60 No refill (to be taken as needed for pain. Rx date 6-18-15) 2. Compound Medication - Ketoprofen 10%/Gabapentin 6%/Bupivacaine 5%/Fluticasone 1%/Baclofen 2%/Cyclobenzaprine 2%/Clonidine 0.2%/Hyaluronic Acid 0.2% No Refill (apply 1-2 pumps a day to affected area .Rx date 6/18/15). 3. Metabolic Supplements - Alph Lipoic Acid 125mg, Folic Acid 0.5mg Hyaluronic Acid-Methylcobalarmin (B12) 0.5mg, Pyridoxal 5/Phosphate 35mg, Resveratrol 25mg-Ubiquinol (Co Q10) 50mg, Vitamin D3 500IU, no refill (Rx date 6/18/15) 4. Compounded Shockwave Cream - Pentoxifyline 5%/Aminophylline 3%/Lidocaine 2.5%, Hyaluronic Acid 1% #240mg, no refill (apply 3-4 times daily Rx 6/18/15). A utilization review decision on 8-26-2015 non-certified the request in its entirety.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ibuprofen 600mg #60 No refill (to be taken as needed for pain rx date 6/18/15): Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steriodal anti-inflammatory drugs).

Decision rationale: The MTUS recommends NSAIDs at the lowest dose for the shortest period in patients with moderate to severe pain. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. It does not appear that the patient is taking any other oral medications for pain. I am reversing the previous utilization review decision. Ibuprofen 600mg #60 No refill (to be taken as needed for pain rx date 6/18/15) is medically necessary.

Compound Medication - Ketoprofen 10%/Gabapentin 6%/Bupivacaine 5%/Fluticasone 1%/Baclofen 2%/Cyclobenzaprine 2%/Clonidine 0.2%/Hyaluronic Acid 0.2% No Refill (apply 1-2 pumps a day to affected area rx date 6/18/15): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: According to the MTUS, there is little to no research to support the use of many of these compounded topical analgesics. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Ketoprofen agent is not currently FDA approved for a topical application. It has an extremely high incidence of

photo contact dermatitis. Compound Medication - Ketoprofen 10%/Gabapentin 6%/Bupivacaine 5%/Fluticasone 1%/Baclofen 2%/Cyclobenzaprine 2%/Clonidine 0.2%/Hyaluronic Acid 0.2% is not medically necessary.

Metabolic Supplements - Alph Lipoic Acid 125mg, Folic Acid 0.5mg Hyaluronic Acid-Methylcobalarmin (B12) 0.5mg, Pyridoxal 5/Phosphate 35mg, Resveratrol 25mg-Ubiquinol (Co Q10) 50mg, Vitamin D3 500IU, no refill (rx date 6/18/15): 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, 2015.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Medical food.

Decision rationale: Medical food is defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." Medical foods do not have to be registered with the FDA and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. Alph Lipoic Acid 125mg, Folic Acid 0.5mg Hyaluronic Acid-Methylcobalarmin (B12) 0.5mg, Pyridoxal 5/Phosphate 35mg, Resveratrol 25mg-Ubiquinol (Co Q10) 50mg, Vitamin D3 500IU is not medically necessary.

Compounded Shockwave Cream - Pentoxifyline 5%/Aminophylline 3%/Lidocaine 2.5%, Hyaluronic Acid 1% #240mg, no refill (apply 3-4 times daily rx 6/18/15): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: According to the MTUS, there is little to no research to support the use of many of these compounded topical analgesics. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The MTUS also states that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Compounded Shockwave Cream - Pentoxifyline 5%/Aminophylline 3%/Lidocaine 2.5%, Hyaluronic Acid 1% #240mg is not medically necessary.