

Case Number:	CM14-0108240		
Date Assigned:	08/01/2014	Date of Injury:	09/04/2012
Decision Date:	09/09/2014	UR Denial Date:	06/23/2014
Priority:	Standard	Application Received:	07/11/2014

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 Physical Medicine and Rehabilitation and is licensed to practice in Texas and Ohio. 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 injured worker is a 53-year-old female who reported injury on 09/04/2012. The documentation indicated the injured worker was utilizing Ketoprofen in PLO gel, Cyclophene 5% in PLO gel, Synapryn, Tabradol, Deprizine, Dicopanol and Fanatrex as of 11/2013. The mechanism of injury was not provided. The injured worker's complaints, as of 03/21/2014, included dull, boring, bilateral wrist and hand pain that was constant and moderate to severe. The injured worker had burning radicular low back pain and muscle spasms that were constant and moderate to severe. The injured worker had burning bilateral foot pain 5/10 to 6/10, moderate to severe. The injured worker indicated that the symptoms persisted, but the medications offered a temporary relief of pain and an improvement in her ability to have a restful sleep. The physical examination revealed generalized tenderness over the bilateral hands. The injured worker had decreased range of motion and a positive Phalen's bilaterally in the wrists and hands. There were decreased myotomes bilaterally. The physical examination of the lumbar spine revealed tender paraspinals at the lumbosacral junction and decreased range of motion. The injured worker had decreased range of motion of the bilateral ankles, as well as decreased sensation and myotomes. The diagnoses included bilateral wrist sprain/strain, rule out bilateral carpal tunnel syndrome, lumbar disc displacement, herniated nucleus pulposus, spondylolisthesis lumbar region, rule out radiculopathy, bilateral foot sprain/strain, mood disorder, anxiety, stress, hypertension, and diabetes mellitus type 2. The treatment plan included the use of medications and that the medications would be monitored for effectiveness and possible dependency. Additionally, it was indicated that UA toxicology evaluations would be performed. The treatment plan also included a course of acupuncture and chiropractic treatment for the right and left hands and wrists, lumbar spine and bilateral feet.

IMR ISSUES, DECISIONS AND RATIONALES

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

Compounded Ketoprofen 20% In PLO gel 120gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants, Topical applications.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Ketoprofen Page(s): 111-113.

Decision rationale: The California MTUS guidelines indicates that topical analgesics are largely experimental in use, with few randomized controlled trials to determine efficacy or safety, and any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Ketoprofen is not currently FDA approved for a topical application. The clinical documentation submitted for review indicated the injured worker has utilized the medication since at least 11/2013. There was a lack of documentation of efficacy for the requested medication. The request, as submitted, failed to indicate the frequency for the requested medication. Given the above, the request for compounded Ketoprofen 20% in PLO gel 120gm is not medically necessary.

Compounded Cyclophene 5% in PLO gel 120gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Topical Muscle Relaxants, Cyclobenzaprine Page(s): 111-113, 41.

Decision rationale: The California MTUS guidelines indicate that topical analgesics are experimental in use, with few randomized controlled trials to determine efficacy or safety, and 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. The guidelines do not recommend the topical use of Cyclobenzaprine as there is no evidence for the use of muscle relaxants as topical products. The clinical documentation submitted for review failed to provide a necessity for both topical and oral Cyclobenzaprine. The documentation indicated the injured worker had utilized the medication since at least 11/2013. There was a lack of documented efficacy for the requested medication. The request, as submitted, failed to indicate the frequency for the requested medication. Given the above, the request for compounded Cyclophene 5% in PLO gel 120gm is not medically necessary.

Synapryn 10mg /1 ml / 500ml: 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 Glucosamine Sulfate, Ongoing Management, Tramadol Page(s): 50, 78, 82, 93, & 94.

Decision rationale: The California MTUS Guidelines recommend Tramadol for pain; however, they do not recommend it as a first-line oral analgesic. They recommend Glucosamine Sulfate for patients with moderate arthritis pain, especially knee osteoarthritis. Also, only one medication should be given at a time. Synapryn, per the online package insert, includes Tramadol and Glucosamine Sulfate. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. The clinical documentation submitted for review failed to indicate the injured worker had moderate arthritis pain. There was a lack of documentation indicating a necessity for Tramadol and Glucosamine Sulfate. The request, as submitted, failed to indicate the frequency for the requested medication. Additionally, as the medication included Tramadol, there would be a necessity for documentation of objective functional benefit and an objective decrease in pain, as well as documentation that the injured worker is being monitored for aberrant drug behavior and side effects. There was a lack of documentation meeting the above criteria. Given the above, the request for Synapryn 10 mg / 1 mL / 500 mL is not medically necessary.

Tabradol 1mg/ml 250ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41.

Decision rationale: Tabradol is a compounding kit for oral suspension of Cyclobenzaprine and MSM (Methylsulfonylmethane). A search of ACOEM, California MTUS guidelines and Official Disability Guidelines, along with the National Guideline Clearinghouse (NCG) and the PubMed database, returned no discussion on Tabradol. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. There was a lack of evidence-based literature to support the oral compounding of Cyclobenzaprine and MSM over the commercially available oral forms, and a lack of medical evidence that the patient requires an oral suspension of these medications. The clinical documentation submitted for review failed to provide documentation of a necessity for both topical and oral Cyclobenzaprine. The request, as submitted, failed to indicate the frequency for the requested medication. The clinical documentation indicated the injured worker had utilized this medication since at least 11/2013. Given the above, the request for Tabradol 1 mg/mL 250 mL is not medically necessary.

Deprizine 15mg/ml 250ml: 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 H-2 Blockers Page(s): 69. Decision based on Non-MTUS Citation online resource www.drugs.com/search.php?searchterm=Deprizine.

Decision rationale: The California MTUS Guidelines recommends Histamine 2 blockers for the treatment of dyspepsia secondary to NSAID therapy. The medication Deprizine includes Ranitidine which is a Histamine 2 blocker and can be used for the treatment of dyspepsia. However, per Drugs.com, Deprizine (generic name: Ranitidine hydrochloride) has not been found by the FDA to be safe and effective, and this labeling has not been approved by FDA. The clinical documentation submitted for review indicates the injured worker has utilized the medication since at least 11/2013. There was a lack of documentation indicating exceptional factors to warrant non-adherence to FDA guidelines and recommendations. There was a lack of documented efficacy. The request, as submitted, failed to indicate the frequency for the requested medication. Given the above, the request for Deprizine 15 mg/mL 250 mL is not medically necessary.

Dicopanol (Diphenhydramine) 5mg/ml 150ml: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation The Expert Reviewer based his/her decision on the Non-MTUS Official Disability Guidelines (ODG) Pain Chapter, Insomnia Treatments, and on the Non-MTUS online resource www.drugs.com/search.php?searchterm=Dicopanol.

Decision rationale: The Official Disability Guidelines (ODG) indicate that sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine) and that tolerance seems to develop within a few days. Per Drugs.com, Dicopanol is diphenhydramine hydrochloride, and it was noted that this drug has not been found by the FDA to be safe and effective and labeling was not approved by the FDA. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. There was a lack of documentation indicating exceptional factors to warrant non-adherence to FDA guidelines and recommendations. The request, as submitted, failed to indicate the frequency for the requested medication. The duration of use was since at least 11/2013. Given the above, the request for the request for Dicopanol (diphenhydramine) 5 mg/mL 150 mL is not medically necessary.