

Case Number:	CM13-0062436		
Date Assigned:	12/30/2013	Date of Injury:	12/17/2012
Decision Date:	05/16/2014	UR Denial Date:	11/15/2013
Priority:	Standard	Application Received:	12/06/2013

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 Anesthesiology, Pain Medicine and is licensed to practice in Florida. 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 65-year-old female who reported an injury on 10/17/2012. The documentation indicated the injured worker had been utilizing Deprizine, Dicopropanol, Fanatrex, Synapryn, Tabradol, Cyclophene, and Ketoprofen since 06/2013. The documentation of 09/11/2013 revealed the injured worker's mechanism of injury was being tripped by a child riding a tricycle. The injured worker had complaints of sharp and pulsating headaches, sharp burning left shoulder pain, sharp burning pain at the left side of her anterior chest, and sharp burning lower back pain. The diagnoses included headaches, left shoulder sprain/strain, rib sprain/strain, difficulty breathing, costochondritis, lumbar spine HNP, lumbar radiculopathy, and sleep and mood disorders. The recommendations and treatment included medication refills, physical chiropractic treatment, shockwave therapy, sleep study, referral to an orthopedic surgeon, and referral to a psychologist for a consultation.

IMR ISSUES, DECISIONS AND RATIONALES

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

COMPOUNDED KETOPROFEN 20%,120 GRAMS: 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, Ketoprofen Page(s): 111-112.

Decision rationale: The Expert Reviewer's decision rationale: California MTUS indicates Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety ... 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. Ketoprofen is not FDA approved for a topical application. The clinical documentation submitted for review indicated the injured worker had neuropathic pain and had utilized the medication for 3 months. However, there was a lack of documentation indicating the injured worker had trialed and failed antidepressants and anticonvulsants. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for 1 Prescription for Compounded Ketoprofen 20%, 120 grams is not medically necessary.

COMPOUNDED CYCLOPHENE 5%, 120GRAMS: 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, Topical Muscle Relaxants, Cyclobenzaprine Page(s): 111,113,41.

Decision rationale: The Expert Reviewer's decision rationale: California MTUS indicates 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. California MTUS Guidelines do not recommend the topical use of Cyclobenzaprine as topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. The clinical documentation submitted for review failed to indicate the injured worker had a trial and failure of anticonvulsants and antidepressants. It was indicated the injured worker was utilizing the medication for a total of 3 months. There was a lack of documentation of the efficacy for the requested medication. There was a lack of documentation indicating the necessity for both an oral and topical form of cyclobenzaprine. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for 1 Prescription for Compounded Cyclophene 5%, 120 grams is not medically necessary.

SYNAPRYN (10MG/1ML) 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, page 50, Ongoing Management, page 78, Tramadol Page(s): 50,78,82,93-94.

Decision rationale: The Expert Reviewer's decision rationale: California MTUS Guidelines recommend Tramadol for pain; however, do not recommend it as a first-line oral analgesic. 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. California MTUS guidelines recommend Glucosamine Sulfate for patients with moderate arthritis pain especially, knee osteoarthritis and that only one medication should be given at a time. Synapryn per the online package insert included Tramadol and glucosamine sulfate. Clinical documentation submitted for review failed to provide the necessity for an oral suspension which included Tramadol and glucosamine sulfate. There should be documentation of an objective improvement in function, an objective decrease in pain, and evidence that the patient is being monitored for aberrant drug behavior and side effects. 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 injured worker had utilized the compound for more than 3 months. The clinical documentation submitted for review failed to indicate the injured worker had osteoarthritis to support the necessity for a compounded product containing glucosamine sulfate. There was a lack of documentation of objective improvement in function, objective decrease in pain, and evidence the injured worker was being monitored for aberrant drug behavior and side effects. Additionally, there was a lack of documentation indicating the injured worker had an inability to swallow or tolerate pills. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for 1 Prescription for Synapryn (10 mg/1 ml) 500 ml is not medically necessary.

TABRADOL 1MG/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 Cyclobenzaprine Page(s): 41.

Decision rationale: The Expert Reviewer's decision rationale: California MTUS indicate that Cyclobenzaprine (Flexeril®) is recommended for a short course of therapy. This medication is not recommended to be used for longer than 2-3 weeks. The addition of cyclobenzaprine to other agents is not recommended. They do not recommend the topical use of Cyclobenzaprine as topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. Tabradol is a compounding kit for oral suspension of cyclobenzaprine and methylsulfonylmethane. A search of ACOEM, California MTUS guidelines and Official Disability Guidelines, along with the National Guideline Clearinghouse (NCG) and the PubMed Final Determination Letter for IMR Case Number [REDACTED] 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 for the oral compounding of cyclobenzaprine and methylsulfonylmethane over the commercially available oral forms and the lack of medical necessity requiring an oral suspension of these medications. The clinical documentation submitted for review failed to provide

documentation of a necessity for 2 forms of cyclobenzaprine, a topical and an oral form. The request as submitted failed to indicate the frequency for the medication. There was a lack of documented efficacy as the injured worker was noted to be utilizing the medication for more than 3 months. Given the above, the request for 1 Prescription 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 NSAIDs Page(s): 69.

Decision rationale: The Expert Reviewer's decision rationale: California MTUS Guidelines recommends Histamine 2 blockers for treatment of dyspepsia secondary to NSAID therapy. The clinical documentation submitted for review indicated the medication Deprizine includes ranitidine which is a Histamine 2 blocker and can be used for the treatment of dyspepsia. 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 injured worker had been utilizing the medication for more than 3 months. The clinical documentation submitted for review failed to indicate the injured worker had signs and symptoms of dyspepsia secondary to NSAID therapy. There was a lack of documentation indicating the injured worker was taking an oral form of NSAIDs. There was a lack of documentation indicating the injured worker had an inability to swallow or tolerate a pill. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for 1 Prescription for Deprizine 15 mg/ml 250 ml is not medically necessary.