

Case Number:	CM14-0011467		
Date Assigned:	02/21/2014	Date of Injury:	08/08/2012
Decision Date:	07/28/2014	UR Denial Date:	12/27/2013
Priority:	Standard	Application Received:	01/28/2014

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 Orthopedic Surgery and is licensed to practice in Texas. 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 29 year old male injured on 08/08/12 when he was carrying a bucket weighing approximately 50-60 pounds and twisted feeling a sharp pain in his neck, low back, and testicles. The current diagnoses included cervical/lumbar spine HNP and radiculopathy, and left testicle pain rule out varicocele. Clinical note dated 11/27/13 indicated the injured worker presented with continued complaints of sharp neck pain and muscle spasms rated 6-7/10 radiating to the shoulders with associated numbness and tingling. The injured worker also complained of sharp, stabbing, burning low back pain and muscle spasms rated 7-8/10 with associated numbness and tingling of bilateral lower extremities. The injured worker reported burning pain of the left testicle rated 4-5/10 aggravated with bending and twisting at the waist and coughing sneezing. The injured worker reported symptoms persisted; however, the medications offered him temporary pain relief and improved his ability to have restful sleep. Physical examination revealed slightly diminished sensation to pin prick over L4 and L5 dermatomes in the right lower extremity, decreased L2 through S1 motor strength with bilateral lower extremities second to pain, deep tendon reflexes 2+ and symmetrical in bilateral lower extremities, decreased muscle strength at C5 to T1 secondary to pain in bilateral upper extremities, and positive straight leg raise bilaterally. Medications prescribed included Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Cyclophene, and Ketoprofen cream. The initial request for compound Cyclophene 5% in PLO gel 120g, compound Ketoprofen 205 and PLO gel 120g, Deprizine 15mg/mL oral suspension 250mL, Dicopanol (Diphenhydramine) 5mg/mL oral suspension 150mL, Fanatrex (Gabapentin) 25mg/mL oral suspension 420mL, Synapryn 10mg/mL oral suspension 500mL, and Tabradol 1mg/mL oral suspension 250mL was initially non-certified on 12/27/13.

IMR ISSUES, DECISIONS AND RATIONALES

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

COMPOUND CYCLOPHENE 5% IN PLO GEL 120 GRAMS.: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 110-111, 113.

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

Decision rationale: As noted on page 111 of the Chronic Pain Medical Treatment Guidelines, the safety and efficacy of compounded medications has not been established through rigorous clinical trials. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is no indication in the documentation that these types of medications have been trialed and/or failed. Further, California MTUS, Food and Drug Administration, and Official Disability Guidelines require that all components of a compounded topical medication be approved for transdermal use. In addition, there is no evidence within the medical records submitted that substantiates the necessity of a transdermal versus oral route of administration. Therefore Compound Cyclophene 5% IN PLO GEL 120 GRAMS cannot be recommended as medically necessary as it does not meet established and accepted medical guidelines.

COMPOUND KETOPROFEN 205 IN PLO GEL 120GRAMS.: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 112.

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

Decision rationale: As noted on page 111 of the Chronic Pain Medical Treatment Guidelines, the safety and efficacy of compounded medications has not been established through rigorous clinical trials. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is no indication in the documentation that these types of medications have been trialed and/or failed. Further, California MTUS, Food and Drug Administration, and Official Disability Guidelines require that all components of a compounded topical medication be approved for transdermal use. Ketaprofen contains has not been approved for transdermal use. In addition, there is no evidence within the medical records submitted that substantiates the necessity of a transdermal versus oral route of administration. Therefore Compound Ketoprofen 205 IN PLO GEL 120GRAMS cannot be recommended as medically necessary as it does not meet established and accepted medical guidelines.

DEPRIZINE 15MG/ML ORAL SUSPENSION 250ML.: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 68 and 69.

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

Decision rationale: As noted in the Official Disability Guidelines - Online version, Pain Chapter, proton pump inhibitors are indicated for patients at intermediate and high risk for gastrointestinal events with concurrent use of non-steroidal anti-inflammatory drug use. Risk factors for gastrointestinal events include age > 65 years; history of peptic ulcer, GI bleeding or perforation; concurrent use of ASA, corticosteroids, and/or an anticoagulant; or high dose/multiple NSAID (e.g., NSAID + low-dose ASA). There is no indication that the injured worker is at risk for gastrointestinal events requiring the use of proton pump inhibitors. Furthermore, long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture. Moreover, there is no indication in the documentation that the injured worker cannot tolerate the pill formulation of this medication and requires a suspension. As such, the request for Deprizine 15mg/ML Oral Suspension 250ML cannot be established as medically necessary.

DICOPANOL (DIPHENHYDRAMINE) 5MG/ML ORAL SUSPENSION 150 ML: 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), Mental, Under, "Insomnia Treatment".

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness & Stress, Diphenhydramine (Benadryl).

Decision rationale: As noted in the Official Disability Guidelines, sedating antihistamines are not recommended for long-term insomnia treatment. Additionally, there is no documentaion of allergic reaction that would be treated with the diphenhydramine. Further, there is no indication in the documentation that the injured worker cannot tolerate the pill formulation of this medication and requires a suspension. As such, the request for Dicopanol (Diphenhydramine) 5mg/ML Oral Suspension 150 ML cannot be recommended as medically necessary.

FANATREX (GABAPENTIN) 25MG/ML ORAL SUSPENSION 420ML.: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti Epilepsy Drugs Page(s): 49.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin (Neurontin) Page(s): 49.

Decision rationale: As noted on page 49 of the Chronic Pain Medical Treatment Guidelines, current guidelines recommend Gabapentin for the treatment of neuropathic pain. There is no

indication in the documentation that the injured worker cannot tolerate the pill formulation of this medication and requires a suspension. Additionally, there is no documentation of allergic reaction that would be treated with the diphenhydramine. As such, the request for Dicopan^{ol} (Diphenhydramine) 5mg/ML Oral Suspension 150 ML cannot be recommended as medically necessary.

SYNAPRYN 10MG/LML ORAL SUSPENSION, 500 ML.: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 94-95.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Criteria For Use Page(s): 77.

Decision rationale: As noted on page 77 of the Chronic Pain Medical Treatment Guidelines, patients must demonstrate functional improvement in addition to appropriate documentation of ongoing pain relief to warrant the continued use of narcotic medications. There is no clear documentation regarding the functional benefits or any substantial functional improvement obtained with the continued use of narcotic medications. There is no indication in the documentation that the injured worker cannot tolerate the pill formulation of this medication and requires a suspension. As such, the request for Synapryn 10mg/Lml Oral Suspension, 500 ML cannot be recommended as medically necessary.

TABRODOL 1MG/MO ORAL SUSPENSION 250 ML.: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 41, 63.

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

Decision rationale: As noted on page 41 of the Chronic Pain Medical Treatment Guidelines, Cyclobenzaprine is recommended as a second-line option for short-term (less than two weeks) treatment of acute low back pain and for short-term treatment of acute exacerbations in patients with chronic low back pain. There is no indication in the documentation that the injured worker cannot tolerate the pill formulation of this medication and requires a suspension. As such, the medical necessity of Tabrodol 1mg/Mo Oral Suspension 250 ML cannot be established at this time.