MAXIMUS Federal Services

Case Number:	CM13-0061317		
Date Assigned:	12/30/2013	Date of Injury:	08/24/2012
Decision Date:	05/20/2014	UR Denial Date:	11/25/2013
Priority:	Standard	Application Received:	12/04/2013

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 Physical Medicine and Rehabilitation, and is licensed to practice in California. 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 patient is a 44-year-old who was injured on August 24, 2012 while he was in the process of lifting up a jack's end when he felt pain in his lower back. Prior treatment history has included physical and manipulative therapy, acupuncture, injections, and prescribed medications such as ibuprofen, Flexeril, and Lidoderm patch. Comprehensive drug screen dated October 21, 2013 showed test results did not detect any drugs and was consistent with prescribed medications. PR2 dated October 11, 2013 indicated the patient complains of sharp shooting pain that begins at the center of the lumbar spine and radiates down to both lower extremities. The pain causes major discomfort when going about daily activities. The pain worsens when the patient is driving. The pain medications help relieve pain; however; the pain was still constant. Objective findings on exam revealed pain with range of motion in the lower region. There was tenderness to palpation; Positive straight leg raise bilaterally; Laseague's differential was positive bilaterally; positive ELI's test bilaterally. There was decreased motor strength secondary to pain in the lower extremities. The popliteal, dorsalis pedis and posterior tibialis pulses were within normal limits in both lower extremities. The patient was diagnosed with suspect disc herniation, lumbar disc displacement, radicular syndrome of lower limbs, spasm of muscles, and strain of the lumbar region. The patient was awaiting authorization for an orthopedic consult with [redacted] for lumbar spine and for follow up with [redacted] for pain management for oral and topical medication. PR2 dated November 20, 2013 documented the patient to have complaints of burning, radicular low back pain 8/10, constant, moderate to severe; numbness and tingling of the bilateral lower extremities. The patient stated symptoms persisted but the medications did offer temporary relief of pain and improved ability to have restful sleep. He denied any problems with medication. The pain was also alleviated by activity restrictions. Lumbar spine examination revealed heel-toe walk revealed pain on the walking. He was tender over the

quadratuslumborum muscles with a trigger point at the left, lumbosacral junction, right sciatic notch; decreased range of motion; flip and Laseque's bill POS. The patient was diagnosed with lumbago and lumbar spine radiculopathy.

IMR ISSUES, DECISIONS AND RATIONALES

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

COMPOUNDED KETOPROFEN: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113.

Decision rationale: According to the guidelines, Ketoprofen is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis. Only FDA approved are recommended. There is no support to use this over the FDA regulated products. The Chronic Pain Medical Treatment Guidelines states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The request for compounded Ketoprofen is not medically necessary or appropriate.

COMPOUNDED CYCLOPHENE 5%: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113.

Decision rationale: According to the guidelines, muscle relaxants, such as cyclobenzaprine, are not recommended in topical formulation. According to the Chronic Pain Medical Treatment Guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The request for compounded Cyclophene 5% is not medically necessary or appropriate.

SYNAPRYN SUSPENSION 10MG/ML: 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 Opioids Seciont and the Opioids Specific Drug List Section Page(s): 82-83, 93-94. Decision based on Non-MTUS Citation Non-MTUS webpage http://fdb.rxlist.com/drugs/.

Decision rationale: According to the medical literature, Synapryn is a oral suspension containing Tramadol. According to the Chronic Pain Medical Treatment Guidelines, Tramadol (UltramÂ®) is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic, it is indicated for moderate to severe pain. The medical records do not establish this patient is unable to tolerate standard oral medicaions. The request for Synapryn suspension 10 mg/ml is not medically necessary or appropriate.

TRABADOL 1MG/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 Opioids Section Page(s): 74-96.

Decision rationale: An exhaustive Internet search was unable to located you know of any medication named Trabadol. According to the FDA.gov a medication named names trabadol does not exist. It is presumed that this is a compounded product that contains tramadol and some other product or products. However the medical records do not substantiate medical necessity for compounding oral synthetic opioid, especially with other unknown agents, when standard tramadol is available. The request for Trabadol 1 mg/250 ml is not medically necessary or appropriate.

DEPRIZINE 15MG/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 (non-steroidal andti-inflammatory drugs), GI (gastrointestinal) Symptoms & Cardiovascular. Decision based on Non-MTUS Citation Non-MTUS Official Disability Guidelines (ODG), Pain Chapter, Proton Pump Inhibitors (PPIs) Section, and the website WebMD.com.

Decision rationale: Accordign to the medical literature, Deprizine is an oral suspension containing rantidine (zantac). According to the guidelines, proton pump inhibitors, such as Omeprazole, are recommended for patients at risk for gastrointestinal events. Determining factors are 1) age over 65 years, 2) history of peptic ulcer, GI bleeding or perforation, 3) concurrent use of ASA, corticosteroids, and/or an anticoagulants, or 4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA [acetylsalicylic acid]). The medical records do not establish any of these risk factors are present in the case of this patient. The medical records do not establish this patient is at notable risk for GI events. All other agents should be considered second-line therapy. Furthermore, the medical records do not establish medical necessity for oral suspension formulation. The request for Deprizie 15 mg/250 ml is not medically necessary or appropriate.

FANATREX 25MG/420ML: 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 ANTIEPILEPSY DRUGS (AEDS) Page(s): 16, 18.

Decision rationale: anatrex is an oral suspension formulation of gabapentin. According to the guidelines, an anti-epilepsy drug (AED), such as Gabapentin, is recommended for neuropathic pain (pain due to nerve damage). Gabapentin has been shown to be effective for treatment of diabetic painful neuropathy and post-herpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. The medical records do not establish the patient has neuropathic pain. There lacks specific subjective complaints with correlative objective clinical findings, and/or corroborative electrodiagnostic evidence to establish active neuropathy is present. Furthermore, the medical records do not establsh the patient is unable to tolerate standard gabapentin. The request for Fantrex 25 mg/420 ml is not medically necessary or appropriate.

DICOPANOL 5MG/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 Official Disability Guidelines (ODG), Pain Chapter, Insomnia Treatment Section. OTHER MEDICAL TREATMENT GUIDELINE OR MEDICAL EVIDENCE: Fusionpharmallc.com and the webpage www.nlm.nih.gov/medlineplus/druginfo/meds/A682.

Decision rationale: Dicophanol is an oral suspension, active Ingredient: diphenhydramine hydrochloride, manufactured by Fusion pharmaceuticals. Diphenhydramine is an antihistamine, its primary use is to relieve red, irritated, itchy, watery eyes; sneezing; and runny nose caused by hay fever, allergies, or the common cold. According to Official Disability Guidelines, sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine). Tolerance seems to develop within a few days. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. The medical records do not demonstrate this patient presents with any of these symptoms or describes any such complaints for which this active ingredient is recommended to treat. In the absence of documented allergy, cough or cold symptoms, or diagnosed insomnia, the medical necessity of this medication has not been established. Furthermore, the medical records do not establish the patient is unable to tolerate standard, FDA regulated oral medications. The request for Dicopanol 5 mg/150 ml is not medically necessary or appropriate.