MAXIMUS Federal Services

Case Number:	CM14-0029579		
Date Assigned:	04/09/2014	Date of Injury:	02/24/2012
Decision Date:	05/27/2014	UR Denial Date:	12/22/2013
Priority:	Standard	Application Received:	01/21/2014

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 Occupational Medicine 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 an employee of Deploy HR and has submitted a claim for lumbar spine sprain/strain rule out HNP, rule out lumbar radiculopathy associated with an industrial injury on February 24, 2012. Treatment to date includes oral and topical analgesics, muscle relaxant, acupuncture, physical therapy, shockwave therapy, and lumbar epidural steroid injection. Utilization review dated December 22, 2013 denied request for Synapryn 10mg/1mL 500mL because the FDA has not found this drug to be safe and effective and labelling was not approved. There is no clear rationale identifying why a compounded oral suspension is needed for this patient. Request for Tabradol 1mg/mL 250mL was denied because it contains methylsulfonylmethane (MSM), a drug class that is not recommended. Deprizine 15mg/mL 250mL was non-certified due to no reports of GI dosorders such as peptic ulcer disease that would necessitate an H2 blocker. Request for Dicopanol (diphenhydramine) 5mg/mL 150mL was denied because there are no clinical findings such as insomnia that would support the use of an antihistamine and no rationale was provided for the medical necessity of an oral suspension. Fanatrex (gabapentin) 25mg/mL 420 mL was denied due to no rationale was provided for the medical necessity of an oral suspension. Medical records from 2013 were reviewed and showed complaints of constant, grade 7/10, burning, radicular low back pain and muscle spasms with numbness and tingling of the bilateral lower extremities. On examination, there was decreased range of motion of the lumbar spine (flexion 40 degrees, extension 15 degrees, left lateral flexion 20 degrees, right lateral flfexion 15 degrees, lateral rotation 20 degrees) with positive bilateral straight leg raise at 45 degrees. Pain is aggravated by ADLs such as getting dressed and performing personal hygiene. Motor strength is 4/5 in the bilateral lower extremities with slightly decreased sensation to pin-prick and light touch at the L4, L5 and S1 dermatomes bilaterally. Medications provide temporary relief of pain and improve sleep quality. The patient denies

adverse effects from the medications. Lumbar spine examination show tenderness to palpation over the lumbar paraspinal muscles and the lumbosacral junction. Medications include Synapryn 10mg/1mL for pain unresponsive to first-line treatment, Tabradol 1mg/mL for muscle spasms, Deprizine 15mg/mL for GI pain and prophylaxis against development of gastric ulcer, Dicopanol (diphenhydramine) 5mg/mL for insomnia, Fanatrex (Gabapentin) 25mg/mL, Cyclophene for neuropathic pain and muscle spasms, and Ketoprofen cream for inflammation prescribed as far back as July 2013. The duration and frequency of use of the medications were not specified.

IMR ISSUES, DECISIONS AND RATIONALES

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

SYNAPRYN 10MG/1ML ORAL SUSPENSION 500ML: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Non-MTUS Citation: FDA Synapryn.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Non-MTUS Citation: FDA Synapryn.

Decision rationale: Synapryn (oral suspension) contains tramadol. The California MTUS guidelines do not address tramadol in oral suspension specifically. The FDA has not found Synapryn to be safe and effective. In this case, the records do not indicate that the employee has had a pain assessment to access the effects of this medication. In addition, the records do not indicate why the employee is unable to take oral capsules or tablets requiring the use of a compounded oral suspension. Therefore, the request for Synapryn 10mg/1mL oral suspension 500mL is not medically necessary and appropriate.

TABRADOL 1MG/ML ORAL SUSPENSION 250ML: Upheld

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

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

Decision rationale: The MTUS Chronic Pain Medical Treatment Guidelines state that any compounded product that contains at least one drug (drug class) that is not recommended is not recommended. Tabradol contains cyclobenzaprine and methylsulfonylmethane (MSM), which is not FDA approved. The MTUS does not recommend the use of muscle relaxants in topical formulations. In this case, there was no indication or evidence that a suspension formulation would be more superior to a tablet formulation. Therefore, the request for Tabradol 1mg/mL oral suspension 250mL is not medically necessary and appropriate and appropriate.

DEPRIZINE 15MG/ML ORAL SUSPENSION 250ML: 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 Non-MTUS Citation: FDA (Ranitidine).

Decision rationale: The California MTUS and Official Disability Guidelines (ODG) do not address this issue. The FDA states that ranitidine is an H2 receptor antagonist indicated in the treatment of active gastric or duodenal ulcers, or for endoscopically diagnosed erosive esophagitis. In this case, the records reviewed did not provide any evidence that the employee has been diagnosed with active gastric or duodenal ulcers or erosive esophagitis. There is no discussion concerning the need for variance from the guidelines. In addition, there is no indication as to why the employee is unable to take a pill or capsule orally, and as such, the need for a compounded suspension has not been established. Therefore, the request for Deprizine 15mg/mL oral suspension 250mL is not medically necessary and appropriate.

DICOPANOL (DIPHENHYDRAMINE) 5MG/ML ORAL SUSPENSION 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) Mental Illness And Stress Chapter Insomnia Treatment.

Decision rationale: California MTUS Guidelines does not address this issue. The Official Disability Guidelines (ODG) Mental Illness & Stress Chapter, Insomnia treatment state that sedating antihistamines have been suggested for sleep aids, but tolerance seems to develop within a few days. The ODG guidelines further state next day sedation has also been noted as well as impaired psychomotor and cognitive functions. In this case, records provided indicate that the pain medication regimen of the patient helps decrease the pain and improve sleep quality however there are no clinical findings such as insomnia that would support the use of an antihistamine. In addition, there is no indication as to why the employee cannot take an oral tablet and pill and requires an oral suspension. Therefore, the request for Dicopanol (diphenhydramine) 5mg/mL oral suspension 150mL is not medically necessary and appropriate.

FANATREX: 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 Page(s): 16-17.

Decision rationale: The California MTUS Chronic Pain Medical Treatment Guidelines, Gabapentin has been considered as a first-line treatment for neuropathic pain. After initiation of

treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. In this case, the patient has been using Gabapentin (Fanatrex) as far back as July 2013 however duration and frequency of use were not specified. Continued use of Gabapentin is not recommended as specific functional gains or analgesia was not documented such as improved ability to perform activities of daily living. In addition, there is no indication as to why the employee cannot take an oral tablet and pill and requires an oral suspension. There is no discussion concerning the need for variance from the guidelines. Therefore, the request for Fanatrex is not medically necessary and appropriate.