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| Case Number: | CM13-0001330 | | |
| Date Assigned: | 05/02/2014 | Date of Injury: | 11/02/2011 |
| Decision Date: | 06/09/2014 | UR Denial Date: | 07/01/2013 |
| Priority: | Standard | Application Received: | 07/12/2013 |

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 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 a 39 year old male who was injured on 11/02/2011 while he was attempting to put a propane tank onto a booth. When he lifted the tank he strained his lower back in the process. Prior treatment history has included physical therapy, lumbar fusion and medications. Diagnostic studies reviewed include urine drug screen dated 03/31/2014 revealing positive detection of tramadol being inconsistent. A urine drug screen dated 04/25/2014 revealing positive detection of tramadol, which is inconsistent, and hydrocodone, which is consistent. A PR-2 dated 03/25/2014 documented the patient is status post lumbar fusion with residual pain, 7/10. He has numbness and tingling in the right lower extremity. He is experiencing stress, anxiety and depression. The patient states that the symptoms persist but the medications do offer temporary relief of pain and improve his ability to have restful sleep. He denies any problems with the medications. The pain is also alleviated by activity restrictions. Objective findings on examination of the lumbar spine reveal well healed surgical incisions. He is unable to perform heel-toe walk. There is 2+ tenderness at the lumbar bilateral PSISs, bilateral lumbar paraspinal muscle guarding and decreased ROM of the lumbar spine. There is positive SLR and Braggard's. Diagnoses include status post lumbar fusion, lumbar HNP, lumbar radiculopathy, anxiety disorder, mood disorder, and stress.

IMR ISSUES, DECISIONS AND RATIONALES

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

**COMPOUND: AMITRIPTYLINE/DEXTROMETHORPHAN/TRAMADOL 4/20/5%
CREAM QUANTITY 1.00: Upheld**

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Physician's Desk Reference, Amitriptyline Topical.

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

Decision rationale: According to the MTUS Chronic Pain Guidelines, topical analgesics are an option with specific indications; many agents are compounded as monotherapy or in combination for pain control. The records provided fail to establish any of these ingredients in topical formulation are medically necessary for the management of this patient's complaints. The medical records do not provide a rationale that establishes the medical necessity for a compounded topical containing a cough suppressant, antidepressant and synthetic opioid in a topical compound. Thus, the request is not medically necessary and appropriate.

COMPOUND: CAPS/DICLO/MENTHOL/CAMPHOR 0.0375/20/2/2% QUANTITY 1.00:
Upheld

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

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

Decision rationale: According to the MTUS Chronic Pain Guidelines, Capsaicin is appropriate and medically necessary for patients that are intolerant to first-line therapies, which is not the case for this patient. In addition, there have been no studies of a 0.0375% formulation of Capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. The only FDA approved topical agent containing Diclofenac is Voltaren® Gel 1%, which is indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). Only FDA-approved products are currently recommended. The MTUS Chronic Pain Guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Thus, the requested compound topical agent is not medically necessary and appropriate.

DICLOFENAC CREAM 20% QUANTITY 1.00: Upheld

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

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

Decision rationale: According to the MTUS Chronic Pain Guidelines, the only FDA-approved topical agent containing Diclofenac is Voltaren[®] Gel 1% (Diclofenac), which is indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Only FDA-approved products are currently recommended. As per the MTUS Chronic Pain Guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the requested Diclofenac cream is not medically necessary and appropriate.

SYNAPRYN 10 MG/1 ML ORAL SUSPENSION 500 ML QUANTITY 1.00: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 75.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 82-83, 93-94.

Decision rationale: Synapryn is a oral suspension containing Tramadol. According to the MTUS Chronic Pain Guidelines, Tramadol (Ultram[®]) 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 medications. Medical necessity for a liquid suspension has not been established. The request is therefore not medically necessary and appropriate.

DEPRIZINE 15 MG/ML ORAL SUSPENSION 250 ML QUANTITY 1.00: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines , Treatment Index.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68-69.

Decision rationale: Deprizine is an oral suspension containing Rantidine (zantac). According to the MTUS Chronic Pain 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). 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 has a notable risk for GI events. All other agents, including Zantac, should be considered second-line therapy. Furthermore, the medical records do not establish medical necessity for an oral suspension formulation. The request is not medically necessary and appropriate.

TABRADOL1 MG/1 ML ORAL SUSPENSION 250 ML QUANTITY 1.00: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Muscle relaxants Page(s): 41-42, 63.

Decision rationale: Tabradol is a suspension formulation containing cyclobenzaprine hydrochloride as the active ingredient. According to the MTUS Chronic Pain Guidelines, Cyclobenzaprine is recommended as a short course of therapy only. Muscle relaxants should be considered as a second-line option to treat exacerbations. The medical records do not establish the presence of spasms on examination or that the patient has presented with any acute exacerbation of chronic pain. Furthermore, the medical records do not establish the patient is unable to tolerate standard oral medications. The medical necessity of Trabadol is not established.

DICOPANOL 5 MG/ML ORAL SUSPENSION 150 ML QUANTITY 1.00: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Treatment Index.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), http://fusionpharmallc.com/main/page_home.html, and <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a682539.html>.

Decision rationale: Dicophanol is an oral suspension manufactured by Fusion pharmaceuticals with the active ingredient diphenhydramine hydrochloride. Diphenhydramine is an antihistamine, used to relieve red, irritated, itchy, watery eyes; sneezing; and runny nose caused by hay fever, allergies, or the common cold. According to the ODG, 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 active ingredient has not been established. Furthermore, the medical records do not establish the patient is unable to tolerate standard oral medications. The request is not medically necessary and appropriate.

FANATREX 25 MG/ML ORAL SUSPENSION 420 ML QUANTITY 1.00: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain-Gabapentin Page(s): 18-20. Decision based on Non-MTUS Citation Meds.com.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy Drugs Page(s): 16-18.

Decision rationale: According to the MTUS Chronic Pain 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 postherpetic 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 establish the patient is unable to tolerate standard oral medications. The medical necessity for an oral suspension is not established. The request is not medically necessary and appropriate.