MAXIMUS Federal Services

Case Number:	CM13-0028190		
Date Assigned:	01/24/2014	Date of Injury:	03/29/2007
Decision Date:	06/06/2014	UR Denial Date:	08/26/2013
Priority:	Standard	Application Received:	09/23/2013

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 & 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 53 year old male injured on 03/29/07 due to an undisclosed mechanism of injury. It was noted that the patient was status post lumbar fusion with residual pain, numbness, tingling, and pain radiating to the bilateral lower extremities. The patient reported symptoms persisted; however, medications offered temporary relief of pain and improved ability to have restful sleep. Physical examination revealed decreased sensation to pin prick and light touch slightly diminished over the L4, L5, and S1 dermatomes in bilateral lower extremities, motor strength decreased secondary to pain in all muscle groups of the bilateral lower extremities, deep tendon reflexes 2+ in bilateral lower extremities, and pulses 2+ and symmetrical in bilateral lower extremities. Current medications included Deprizine, Dicopanol, Fanatrex, Synapryn, Tobradol, Cyclophene, and Ketoprofen cream. A 8/26/13 utilization review report recommended non-certification of these requests.

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: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 112-113.

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

Decision rationale: The MTUS Chronic Pain Guidelines cites that topical NSAIDs are indicated for "Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use." That has not been documented. Additionally, topical Ketoprofen is "not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis." Furthermore, there is no clear rationale for the use of topical medications rather than the FDA-approved oral forms for this patient. In light of the above issues, the currently requested compounded Ketoprofen 20% 120 grams is not medically necessary and appropriate.

COMPOUNDED CYCLOPHENE 5% 120 GRAMS: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 112-113.

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

Decision rationale: The MTUS Chronic Pain Guidelines notes that there is no evidence for use of a muscle relaxant as a topical product. Furthermore, there is no clear rationale for the use of topical medications rather than the FDA-approved oral forms for this patient. In light of the above issues, the currently requested compounded Cyclophene 5% 120 grams is not medically necessary and appropriate.

SYNAPRYN 10MG 500ML: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22434.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 50,76-79.

Decision rationale: Regarding the request for Synapryn 10mg 500ml, this compound is noted to contain Tramadol and Glucosamine. With regard to opioids such as Tramadol, the MTUS Chronic Pain Guidelines state that, due to high abuse potential, close follow-up is recommended with documentation of analgesic effect, objective functional improvement, side effects, and discussion regarding any aberrant use. The MTUS Chronic Pain Guidelines go on to recommend discontinuing opioids if there is no documentation of improved function and pain. With regard to glucosamine, it is recommended as an option in patients with moderate arthritis pain, especially for knee osteoarthritis. Within the documentation available for review, there is no indication that the medication is improving the patient's function or pain (in terms of percent reduction in pain or reduced NRS), no documentation regarding side effects, no discussion regarding aberrant use,

and no documentation of knee osteoarthritis. In the absence of such documentation, the current request is not medically necessary and appropriate.

TABRADOL 1MG 250ML: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22434.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 63-66.

Decision rationale: Regarding the request for Tabradol 1mg 250ml, the MTUS Chronic Pain Guidelines support the use of nonsedating muscle relaxants to be used with caution as a 2nd line option for the short-term treatment of acute exacerbations of pain. Within the documentation available for review, there is no identification of a specific analgesic benefit or objective functional improvement as a result of the medication. Additionally, it does not appear that this medication is being prescribed for the short-term treatment of an acute exacerbation, as recommended by guidelines, and there is no clear rationale for the use of this oral suspension compounded kit rather than the FDA-approved oral tablet form. In light of the above issues, the currently request is not medically necessary and appropriate.

DEPRIZINE 15MG #250ML: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.drugs.com/pro/depreizine.html.

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

Decision rationale: Regarding the request for Deprizine 15mg #250ml, the MTUS Chronic Pain Guidelines supports H2 blockers for the treatment of dyspepsia secondary to NSAID therapy or for patients at risk for gastrointestinal events with NSAID use. Within the documentation available for review, there is no indication that the patient has complaints of dyspepsia secondary to NSAID use, a risk for gastrointestinal events with NSAID use, or another indication for this medication. Furthermore, there is no clear rationale for the use of this oral suspension compounded kit rather than the FDA-approved oral tablet form. In light of the above issues, the current request is not medically necessary and appropriate.

DICOPANOL 5MG 150ML: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.drugs.com/cdi/diphenhydramine.html.

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 HTTP://WWW.DRUGS.COM/PRO/DIPHENHYDRAMINE-CAPSULES.HTML.

Decision rationale: Regarding the request for Dicopanol 5mg 150ml, the MTUS Guidelines does not address diphenhydramine. ODG notes that sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine). Tolerance seems to develop within a few days. Next-day sedation has been noted as well as impaired psychomotor and cognitive function. The FDA indications for diphenhydramine include use as an antihistaminic, in the management of motion sickness and Parkinson's disease, and as a nighttime sleep-aid. Within the documentation available for review, there is no documentation of any of the abovementioned conditions and a clear rationale for the use of this oral suspension compounded kit rather than the FDA-approved oral capsule form. In light of the above issues, the currently requested Dicopanol 5mg 150ml is not medically necessary and appropriate.

FANATREX 25MG 420ML: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 18-19.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 16-21.

Decision rationale: Regarding request for Fanatrex 25mg 420ml, the MTUS Chronic Pain Guidelines state that antiepilepsy drugs are recommended for neuropathic pain. They go on to state that a good outcome is defined as 50% reduction in pain and a moderate response is defined as 30% reduction in pain. Guidelines go on to state that 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. Within the documentation available for review, there is no identification of any specific analgesic benefit (in terms of percent reduction in pain or reduction of NRS), and no documentation of specific objective functional improvement. Additionally, there is no clear rationale for the use of this oral suspension compounded kit rather than the FDA-approved oral capsule form. In the absence of such documentation, the currently request is not medically necessary and appropriate.