

Case Number:	CM13-0061779		
Date Assigned:	01/15/2014	Date of Injury:	01/05/2008
Decision Date:	04/22/2014	UR Denial Date:	11/26/2013
Priority:	Standard	Application Received:	12/05/2013

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 Internal Medicine and Emergency Medicine and is licensed to practice in Florida. 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:

This patient is a 39-year-old with a date of injury of 01/05/08. A progress report associated with the request for services, dated 09/15/13, identified subjective complaints of low back pain, rated 5/10. The patient walks with a cane. The medications offer temporary relief of pain and more restful sleep. The objective findings included tenderness of the lumbar spine with decreased motor function and sensation of the lower extremities. The diagnoses included status post lumbar fusion with residual pain and lumbar radiculopathy. The treatment has included previous lumbar fusion. Physical therapy was started on 07/09/13, with two (2) sessions per week over four (4) weeks. Functional improvement related to the therapy was not documented. Most of the PR-2s reviewed omitted the medication history. When medications were listed, they did not include a non-steroidal anti-inflammatory drug (NSAID). A Utilization Review determination was rendered on 11/26/13 recommending non-certification of "Ketoprofen 20%; Compounded Cyclophene 5%; Synapryn Oral suspension; Tabradol oral suspension; Deprizine oral suspension; Dicopanol oral suspension; Fanatrex oral suspension; Physical therapy 3x6 for the lumbar spine".

IMR ISSUES, DECISIONS AND RATIONALES

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

COMPOUNDED KETOPROFEN 20%: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

Decision rationale: Ketoprofen 20% is a non-steroidal anti-inflammatory drug (NSAID) that is being used as a topical analgesic. The Chronic Pain Guidelines indicate that topical analgesics are primarily recommended when other modalities could not be tolerated or have failed. They are primarily recommended for neuropathic pain. The efficacy of topical NSAIDs in osteoarthritis has been inconsistent. They have been shown to be superior to placebo during the first two (2) weeks of treatment, but either not afterward, or with diminishing effect over another two (2) week period. The Guidelines also state that there is little evidence to utilize topical NSAIDs for the treatment of osteoarthritis of the spine, hip or shoulder. The only FDA approved topical NSAID is diclofenac. In this case, there is no documentation of neuropathic pain or recommendation for ongoing spinal therapy with topical NSAIDs. Therefore, there is no documented medical necessity for ketoprofen topical.

COMPOUNDED CYCLOPHENE 5%:

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

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

Decision rationale: Cyclophene is a topical agent containing cyclobenzaprine. The Chronic Pain Guidelines indicate that topical analgesics are recommended as an option in specific circumstances. However, they do state that they are "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The Guidelines also indicate that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Cyclobenzaprine 5% cream is a muscle relaxant being used as a topical analgesic. The Guidelines specifically state that there is no evidence for baclofen or any other muscle relaxant as a topical product. Therefore, there is no necessity for the addition of cyclobenzaprine in the topical formulation for this patient.

SYNAPRYN ORAL SUSPENSION: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids and Topical Analgesics Page(s): 86, 93, and 111. Decision based on Non-MTUS Citation Journal of American Medical Association (JAMA)

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308, Chronic Pain Treatment Guidelines Opioids and Tramadol Page(s): 74-83 and 113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Opioids, specific drug list: Tramadol

Decision rationale: Synapryn is an oral compound containing tramadol, which is a centrally acting synthetic opioid analgesic, glucosamine, and other "proprietary ingredients." The Chronic Pain Guidelines related to on-going treatment of opioids state that there should be documentation and ongoing review of pain relief, functional status, appropriate use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. A recent epidemiologic study found that opioid treatment for chronic non-malignant pain did not seem to fulfill any of the key outcome goals including pain relief, improved quality of life, and/or improved functional capacity. The Guidelines also state that with chronic low back pain, opioid therapy "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (> 16 weeks), but also appears limited." Additionally, "There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain." Opioids are not recommended for more than two (2) weeks and the Guidelines further state that tramadol is not recommended as a first-line oral analgesic. The documentation submitted lacked a number of the elements listed above, such as other first-line oral analgesics have been tried and failed. Likewise, if unspecified ingredients in a compound is not recommended, then the compound cannot be recommended. The medical record does not document the medical necessity for Synapryn.

TABRADOL ORAL SUSPENSION: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine and Muscle relaxants (for pain) Page(s): 41-42 and.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain) Page(s): 64.

Decision rationale: Tabradol is a compound containing cyclobenzaprine, which is a muscle relaxant, methylsulfonyl methane, and other "unspecified proprietary ingredients." The Chronic Pain Guidelines indicate that non-sedating muscle relaxants are recommended with caution as a second-line option for the short-term treatment of acute exacerbations of low back pain. They note that in most low-back pain cases, they show no benefit beyond non-steroidal anti-inflammatory drugs (NSAIDs) in pain and overall improvement. Also, there is no additional benefit shown in combination of NSAIDs. Likewise, the efficacy diminishes over time. The Guidelines also indicate that cyclobenzaprine (Flexeril) is indicated as a short course of therapy. Limited, mixed evidence does not allow a recommendation for cyclobenzaprine for chronic use. Though it is noted that cyclobenzaprine is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. They further state that treatment should be brief and that addition of cyclobenzaprine to other agents is not recommended. The Guidelines do note that cyclobenzaprine has been shown to produce a moderate benefit in the treatment of fibromyalgia. The record does not show any evidence of fibromyalgia, and other indications for cyclobenzaprine beyond a short course are not well supported. Likewise, unspecified ingredients in a compound may not be recommended and therefore the compound cannot be recommended. Therefore, the record does not document the medical necessity for Tabradol.

DEPRIZINE ORAL SUSPENSION: 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 anti-inflammatory drugs) Page(s): 68-69.

Decision rationale: Deprizine is a compound containing ranitidine, which is an H₂-receptor antagonist, and other "proprietary ingredients." Proton pump inhibitors (PPIs) are sometimes used for prophylaxis against the gastrointestinal (GI) side effects of non-steroidal anti-inflammatory drugs (NSAIDs) based upon the patient's risk factors. However, H₂-receptor antagonists are not given that recommendation. They are recommended for dyspepsia secondary to NSAID therapy. Also, the use of non-selective NSAIDs without prophylaxis is considered "okay" in patients with no risk factors and no cardiovascular disease. In this case, there is no documentation of dyspepsia or NSAID therapy at the time of the request. Likewise, unspecified ingredients in a compound may not be recommended and therefore the compound cannot be recommended. Therefore, the record does not document the medical necessity for Deprizine.

DICOPANOL ORAL SUSPENSION: 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, Insomnia

Decision rationale: Dicopanor is a compound containing diphenhydramine, which is an antihistamine used for treatment of insomnia, and other "proprietary ingredients." Pharmacologic therapy for insomnia should include documentation of sleep onset, sleep maintenance, sleep quality and next-day functioning. Those aspects were not available in the record. The Official Disability Guidelines indicate 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. Side effects include urinary retention, blurred vision, orthostatic hypotension, dizziness, palpitations, increased liver enzymes, drowsiness, dizziness, grogginess and tiredness." In this case, the already achieved short-term benefits and side effects associated with ongoing therapy do not support medical necessity. Likewise, unspecified ingredients in a compound may not be recommended and therefore the compound cannot be recommended. Therefore, the record does not document the medical necessity for Dicopanor.

FANATREX ORAL SUSPENSION: 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 Anti-epilepsy Drugs and Gabapentin (Neurontin®) Page(s): 16-21 and 49.

Decision rationale: Fanatrex is a compound containing gabapentin, which is an anti-seizure agent, and other "proprietary ingredients." The Chronic Pain Guidelines indicate that this class of agents is recommended for neuropathic pain, but there are few randomized trials directed at central pain and none for painful radiculopathy. The Guidelines also indicate that "A recent review has indicated that there is insufficient evidence to recommend for or against antiepileptic drugs for axial low back pain." The Guidelines also state that the role for gabapentin is for: "...treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered first-line treatment for neuropathic pain." No recommendations are made for specific musculoskeletal etiologies. In this case, there is no documentation for a neuropathic component to the pain, and little evidence to support its use in low back pain and radiculopathy. Likewise, unspecified ingredients in a compound may not be recommended and therefore the compound cannot be recommended. Therefore, the record does not document the medical necessity for Fanatrex (gabapentin) in this case.

PHYSICAL THERAPY THREE (3) TIMES A WEEK FOR SIX (6) WEEKS (18 VISITS) FOR THE LUMBAR SPINE: 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 Physical Medicine Page(s): 98-99.

Decision rationale: The Chronic Pain Guidelines recommend physical therapy with fading of treatment frequency associated with "... active therapies at home as an extension of the treatment process in order to maintain improvement levels." Specifically, for myalgia and myositis, nine to ten (9-10) visits over eight (8) weeks are recommended. For neuralgia, neuritis, and radiculitis, eight to ten (8-10) visits over four (4) weeks are recommended. In this case, the patient has received eight (8) prior physical therapy sessions. However, recommendations are for eight to ten (8-10) sessions, with the recommendation for fading of treatment frequency. Likewise, there is limited documentation for the home therapy component of this approach. Additionally, there is no documentation of significant functional improvement from the prior physical therapy. Therefore, the record does not document the medical necessity for eighteen (18) additional sessions of physical therapy.