MAXIMUS Federal Services

Case Number:	CM14-0138299		
Date Assigned:	09/05/2014	Date of Injury:	04/12/2009
Decision Date:	10/07/2014	UR Denial Date:	08/20/2014
Priority:	Standard	Application Received:	08/26/2014

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 Physical Medicine and Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in Texas. 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 25 year old female who sustained an industrial injury on 4/12/2009, when she slipped and fell while dancing with a customer. She is diagnosed with cervical and lumbar sprain/strain. Treatment has included physiotherapy, myofascial release, acupuncture, Iontophoresis, infrared, Capsaicin patch, and medications. According to the 7/16/2014 evaluation, the patient complains of 5-6/10 head, 6-7/10 neck and 8/10 low back pain and paresthesias. Past medical history and ROS are unremarkable. Examination reveals cervical and lumbar region tenderness, trigger points, restricted active ROM, positive Spurling's and cervical distraction, diminished sensation over C6 and C7 bilaterally, decreased motor strength due to pain, 2+ reflexes, positive SLR at 60 degrees bilaterally. Diagnoses are headaches, cervical and lumbar sprain/strain, cervicalgia, lumbago, and cervical and lumbar disc displacement. Treatment plan is several compound medications, topicals, lumbar brace, TENS, Hot-cold unit, physical therapy and acupuncture 3x6 weeks, and Terocin patches.According to an 8/29/2014 physical therapy follow up report, the patient complains of 7/10 cervical and 8/10 low back pain. Examination findings document cervical and lumbar region tenderness and restricted range of motion.

IMR ISSUES, DECISIONS AND RATIONALES

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

Terocin Patches (dosage and quantity not specified): 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: The CA MTUS state only Lidocaine in the formulation of Lidoderm patch may be considered for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as Gabapentin or Lyrica). The guidelines state no other commercially approved topical formulations of Lidocaine are indicated for neuropathic pain. Only FDA-approved products are currently recommended. The patient's diagnoses are cervical and lumbar IVD displacement and sprain/strain. The medical records do not establish a diagnosis of diabetic neuropathy or neuropathic pain. Topically applied Lidocaine is not recommended for non-neuropathic pain. The patient tolerates standard oral medications. There is no evidence of neuropathic pain condition or failure of standard first-line therapies. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The medical records do not establish this topical patch is medically necessary and appropriate for this patient. The request for Terocin patch is not medically necessary in this case.

Ketoprofen 20% Cream 165gm: 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 CA MTUS guidelines, topical analgesics are an option with specific indications, many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, Capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, adrenergic receptor agonist, Adenosine, cannabinoids, cholinergic receptor agonists, prostanoids, Bradykinin, Adenosine Triphosphate, biogenic amines, and nerve growth factor.There is little to no research to support the use of many of these agents. Ketoprofen is not FDA-approved for a topical application. It has an extremely high incidence of photo contact dermatitis. Only FDA approved are recommended. The CA MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In addition, the medical records clearly document the patient tolerates standard oral analgesics. The medical necessity of this Ketoprofen topical product is not established.

Cyclobenzaprine 5% Cream 100gm: 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 CA MTUS guidelines, topical analgesics are considered to be largely experimental in use with few randomized controlled trials to determine efficacy or safety. The guidelines also state muscle relaxants, such as Cyclobenzaprine, are not recommended in topical formulation. As per the guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Consequently the medical necessity of this topical Cyclobenzaprine cream is not established.

Synapryn 10mg/1ml Oral Suspension 500ml: Upheld

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

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

Decision rationale: Synapryn is an oral suspension that contains the active ingredient Tramadol and other proprietary ingredients According to the CA MTUS, 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. Failure of first line analgesics has not been established. Additionally, the medical records do not establish this patient is unable to tolerate standard oral medications. Medical necessity for a liquid suspension Synapryn has not been established.

Tabradol 1mg/ml Oral Suspension 250ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants, Cyclobenzaprine.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril), page(s) 41; Muscle relaxants (for pain) Page(s): 63.

Decision rationale: Tabradol is a suspension formulation containing Cyclobenzaprine Hydrochloride as the active ingredient. According to the 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 this patient has presented with any acute exacerbation of chronic pain. In addition, the medical records do not document any attempts with self-directed care such as would include heat/ice, range of motion/stretching exercises, and such. Furthermore, the medical records do not establish the patient is unable to tolerate standard oral medications. The medical necessity of Tabradol is not established.

Deprizine 15mg/ml Oral Suspension 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, GI symptoms & cardiovascular risk Page(s): 68-69.

Decision rationale: Deprizine is an oral suspension containing Ranitidine (Zantac) and other proprietary ingredients. 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). However, none of these factors are present in the case of this patient. The medical records do not establish this patient has 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 oral suspension formulation.

Dicopanol 5mg/ml Oral Suspension 150ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic), Insomnia Treatment

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 treatment

Decision rationale: CA MTUS is silent regarding the request. Dicopanol is an oral suspension that contains the active ingredient Diphenhydramine and other proprietary ingredients. Diphenhydramine is an antihistamine; it is used to relieve red, irritated, itchy, watery eyes; sneezing; and runny nose caused by hay fever, allergies, or the common cold. According to 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 medical necessity of Dicopanol is not established.

Fanatrex 25mg/ml Oral Suspension 420ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs) Page(s): 16,18.

Decision rationale: Fanatrex is an oral suspension, containing active ingredient gabapentin and other proprietary ingredients. According to the CA MTUS 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 medical necessity of Fanatrex has not been established.

1 Hot & Cold Unit: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Neck & Upper Back (Acute & Chronic), Knee & Leg (Acute & Chronic)

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 44. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Low Back, Cold/heat packs; Continuous-flow cryotherapy, Heat therapy

Decision rationale: According to the CA MTUS/ACOEM and Official Disability Guidelines, heat and cold packs are recommended as an option for pain. At-home local applications of cold packs in first few days of acute complaint; thereafter, applications of heat packs or cold packs. There is inadequate clinical evidence to substantiate that a hot/cold unit is more efficacious than standard ice/cold and hot packs. The references state mechanical circulating units with pumps have not been proven to be more effective than passive hot and cold therapy. Simple at home applications of heat and cold will suffice for delivery of heat or cold therapy. The medical necessity of a hot-cold unit is not established.

1 TENS Unit: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TENS (transcutaneous electrical nerve stimulation).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TENS, chronic pain (transcutaneous electrical nerve stimulation) Page(s): 114-115.

Decision rationale: According to the CA MTUS, TENS is not recommended as a primary treatment modality, but a one-month home-based TENS trial may be considered as a noninvasive conservative option, if used as an adjunct to a program of evidence-based functional restoration, for the following conditions: Neuropathic pain, Phantom limb pain and CRPS II, spasticity, and multiple sclerosis. Based on the medical records provided, this patient does not have any of

these conditions. Furthermore, the medical records do not establish this patient has failed standard interventions. In accordance with the guidelines, the medical necessity for TENS unit has not been established.

6 Localized Intensive Neurostimulation Therapy (LINT) Sessions for the Lumbar Spine: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Low Back-Lumbar & Thoracic (Acute & Chronic)

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 5 Cornerstones of Disability Prevention and Management Page(s): 79.

Decision rationale: According to the CA MTUS/ACOEM, "Under the optimal system, a clinician acts as the primary case manager. The clinician provides appropriate medical evaluation and treatment and adheres to a conservative evidence-based treatment approach that limits excessive physical medicine usage and referral." The CA MTUS, Official Disability Guidelines, and National Guidelines Clearinghouse do not provide any evidence-based recommendations and no scientific literature addresses this request. LINT is not discussed in the MTUS or medical treatment guidelines. There is no scientific evidence establishing the efficacy of this intervention as a form of treatment for any condition. This request is considered experimental, and there is no documentation that provides description of what this procedure is, or how it is intended to cure or relieve the patient's complaint. Consequently, the request for LINT sessions to the lumbar spine is not deemed appropriate or medically necessary.