MAXIMUS Federal Services

Case Number:	CM14-0035805		
Date Assigned:	06/23/2014	Date of Injury:	12/03/2012
Decision Date:	07/22/2014	UR Denial Date:	03/13/2014
Priority:	Standard	Application Received:	03/24/2014

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 and is licensed to practice in Illinois. 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 injured worker is a 27-year-old female who reported an injury on 12/03/2012. The mechanism of injury was noted to be a fall. Her prior treatments included medications, chiropractic care, acupuncture, epidural steroid injection, and transcutaneous electrical nerve stimulation. Her diagnoses were noted to be lumbar spine sprain/strain, 4 mm herniated nucleus pulposus at L4-5, 3 to 4 mm herniated nucleus pulposus at L5-S1, confirm right lower extremity radiculopathy, and sleeplessness secondary to pain. The injured worker had a clinical evaluation on 01/21/2014. The injured worker complained of lower back pain and rated her pain a 6/10 on a numerical pain scale. She associated the pain with numbness and tingling in the left foot. She also reported bilateral lower extremity radiculopathy. The objective findings of the physical examination included pain with cervical spine flexion and extension. She had pain with extension of the right lateral flexion and left lateral flexion. It is noted that there were spasms elicited upon flexion. The treatment plan included acupuncture, Theramine, and topical creams. The provider's rationale for the requested medications was provided within the clinical evaluation dated 01/22/2014. The Request for Authorization for medical treatment was dated 01/22/2014.

IMR ISSUES, DECISIONS AND RATIONALES

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

Urine toxicology screen test: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, screening for risk of addiction (tests).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Drug testing Page(s): 43.

Decision rationale: The request for urine toxicology screen is not medically necessary. The California MTUS Chronic Pain Medical Treatment Guidelines indicate drug testing is recommended as an option to assess for the presence of illegal drugs, or as a step to take before a therapeutic trial of opioids, for ongoing management of opioids, for differentiation (dependence and addiction); for opioids, screening risk of addiction; to determine misuse and addiction of opioids. Within the documentation provided in the clinical review, it is not noted that the injured worker is at risk for use of illegal drugs. It is also not indicated that the injured worker uses any opioids for management of ongoing pain. The guidelines indicate use of drug testing for steps to take before therapeutic trial of opioids and it is not noted in the clinical evaluation that there is a treatment plan including a trial of opioids. Therefore, the request for urine toxicology screen test is not medically necessary.

Theramine #60: 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 Chapter, Theramine.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Theramine, Medical Food.

Decision rationale: The request for Theramine #60 is not medically necessary. The Official Disability Guidelines indicate Theramine is not recommended. Theramine a medical food from [redacted]. Theramine is a proprietary blend of gamma-aminobutyric acid and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. There is no high quality peer reviewed literature to indicate that the ingredients in Theramine would be useful. The guidelines indicate that until there are higher quality studies of the ingredients in Theramine, it is not recommended. The guidelines continue to recommend medical food if it meets the following criteria: the product must be a food for oral or tube feeding; the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; the product must be used under medical supervision. The injured worker's clinical evaluation does not provide the criteria for medical food under the guidelines. In addition, the request for Theramine fails to provide a dosage and frequency. Therefore, the request for Theramine #60 is not medically necessary.

Topical Cream: Baclofen 2%, Cyclobenzaprine 2%, Ketoprofen 15%, Lidocaine 5%. 240gms (BCKL): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113.

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

Decision rationale: The request for topical cream baclofen 2%, cyclobenzaprine 2%, ketoprofen 15%, lidocaine 5% 240 g is not medically necessary. The California MTUS Chronic Pain Medical Treatment Guidelines state topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The guidelines continue to address topical analgesics by stating that there is little to no research to support the use of many of these agents. A compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. The guidelines indicate that baclofen is not recommended. There is currently a phase 3 study of baclofen-amitriptyline-ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. There is no peer-reviewed literature to support the use of topical baclofen. The requested topical cream contains ketamine. The guidelines indicate that ketamine is under study: Only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted. Lidocaine is recommended 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). Topical lidocaine, in the formulation of a dermal patch has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. It is not indicated in the clinical evaluation that the injured worker has failed trials of antidepressants and anticonvulsants. Therefore, the request for topical cream baclofen 2%, cyclobenzaprine 2%, ketoprofen 15%, lidocaine 5% 240 g is not medically necessary.

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