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| Case Number: | CM13-0021826 | | |
| Date Assigned: | 11/13/2013 | Date of Injury: | 11/22/2012 |
| Decision Date: | 01/14/2014 | UR Denial Date: | 08/06/2013 |
| Priority: | Standard | Application Received: | 09/09/2013 |

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Anesthesiology, has a subspecialty in Pain 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 physician 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 70 year old male injured worker with a date of injury of 11/22/12. He has been diagnosed with multilevel disc herniation and radiculopathy. An MRI dated 6/30/13 demonstrated disc bulges. The patient was refractory to treatment with medication, acupuncture and aquatic therapy. An 8/6/13 note by [REDACTED] noted "Currently, he is not taking oral analgesics for pain control. He states that at this time, he feels that he is not in need of actual medication." A 7/15/13 EMG/NCS showed no evidence of radiculopathy, despite finding of left gastrocnemius atrophy at another date.

IMR ISSUES, DECISIONS AND RATIONALES

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

Pro-Stim 5.0 unit for cervical and lumbar spine: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Transcutaneous Electrotherapy Page(s): 114-117.

Decision rationale: MTUS is silent on this specific device, which may be used to provide TENS as well as NMES therapy, among its multiple modes. Galvanic stimulation and NMES are specifically not recommended by the MTUS. This device has the ability to function in a manner

similar to a TENS unit, however I was not able to find any documentation of a TENS trial nor that the patient is in a functional restoration program. MTUS recommends against NMES, and TENS or interferential current systems as isolated modalities. The request for the Pro-Stim 5.0 unit is not medically necessary and appropriate.

Xoten-C lotion: Upheld

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

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

Decision rationale: Xoten-C lotion contains methyl salicylate 20%, menthol 10%, capsaicin 0.002%. MTUS guidelines state that topical medications 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. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of menthol. Since menthol is not medically indicated, then the overall product is not indicated per MTUS as outlined above. The request for Xoten-C lotion is not medically necessary and appropriate.

Cyclobenzaprine 7.5mg: Upheld

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

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

Decision rationale: Chronic Pain Medical Treatment Guidelines indicate that non-sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. The guidelines also note that treatment with cyclobenzaprine should be brief. The patient is not being treated for an acute exacerbation of chronic back pain, so the requested treatment is not medically necessary. The request for cyclobenzaprine is not medically necessary and appropriate

Tramadol ER 150mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 84.

Decision rationale: MTUS guidelines note that there are no long-term studies to allow for recommendations of the use of Tramadol for longer than three months.(Cepeda, 2006) Similar findings were found in an evaluation of a formulation that combines immediate-release vs. extended release Tramadol. Documentation in support of opiate therapy was lacking. The MTUS has a detailed list of recommendations for initiation and continuation of opioids in the context of efficacy required to substantiate medical necessity, and these recommendations do not appear to have been addressed by the treating physician in the documentation available for review. To reach the MTUS definition of medical necessity for ongoing treatment in the context of safety, efforts to rule out aberrant behavior (ie CURES report, UDS, opiate agreement) and assure safe usage are needed. In regards to safety assurances, CURES report is not addressed in records available. The request for Tramadol ER is not medically necessary and appropriate.

Lidoderm #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 56-57.

Decision rationale: MTUS guidelines indicate that topical lidocaine may be 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). This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. This injured worker has not been diagnosed with post-herpetic neuralgia, nor is there documentation of failure of TCAs/SNRIs/gabapentin/pregabalin. The request for Lidoderm patches is not medically necessary and appropriate.

Medrox #30: Upheld

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

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

Decision rationale: This product contains methyl salicylate, menthol, capsaicin. MTUS guidelines state that topical medications 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. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Any

compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of menthol. Since menthol is not medically indicated, then the overall product is not indicated per MTUS as outlined below. Additionally, the records do not indicate that an antidepressant therapy has been tried and failed. The request for Medroxy patches is not medically necessary and appropriate.