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| Case Number: | CM13-0008606 | | |
| Date Assigned: | 12/18/2013 | Date of Injury: | 07/31/2012 |
| Decision Date: | 03/10/2014 | UR Denial Date: | 07/26/2013 |
| Priority: | Standard | Application Received: | 08/08/2013 |

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 Physical Medicine and Rehabilitation, 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 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 42-year-old female who reported injury on 07/31/2012. The mechanism of injury was stated to be a patient pushed the patient's arm and hurt her. The patient was noted to have complaints of burning radicular neck pain with muscle spasms. The patient's pain was noted to be 6/10. The patient was noted to complain of burning left shoulder pain radiating down the arm to the fingers associated with muscle spasms rated at 7/10. The patient was noted to have burning in the left wrist and muscle spasms. The pain was noted to be constant moderate to severe. It was indicated the patient has symptoms but the medication offered temporary pain relief and ability to improve a restful sleep. The patient's diagnoses were noted to include left eye pain, cervical spine pain, cervical spine HNP, cervical radiculopathy, left shoulder internal derangement, left wrist carpal tunnel syndrome, anxiety disorder, mood disorder, and stress. The request was made for multiple medications, physical therapy, and 8 sessions of shockwave therapy as well as a urine drug screen.

IMR ISSUES, DECISIONS AND RATIONALES

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

Deprizine 15mg 250ml: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Official Disability Guidelines and the National Guideline Clearinghouse.

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

Decision rationale: California MTUS Guidelines recommends Histamine 2 blockers for treatment of dyspepsia secondary to NSAID therapy. The clinical documentation submitted for review indicated the medication Deprizine includes ranitidine which is a Histamine 2 blocker and can be used for the treatment of dyspepsia. The clinical documentation submitted for review failed to indicate the patient had signs or symptoms of dyspepsia secondary to NSAID therapy. There was a lack of documentation of exceptional factors to support the use of the medication. Given the above, the request for 1 prescription of Deprizine 15 mg 250 ml is not medically necessary.

Fanatrex 25mg 420ml: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Official Disability Guidelines and the National Guideline Clearinghouse.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 16. Decision based on Non-MTUS Citation drugs.com.

Decision rationale: California MTUS guidelines indicate that Gabapentin is used in the treatment of neuropathic pain. Per drugs.com, Fanatrex is noted to be an oral suspension of Gabapentin and has not been found to be FDA-safe and effective, and the labeling has not been approved by the FDA. The clinical documentation submitted for review failed to provide exceptional factors as this medication has not been recommended per the FDA. The request for 1 prescription of Fanatrex 25 mg 420 ml is not medically necessary.

Dicopanol 5mg 150ml: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Official Disability Guidelines and the National Guideline Clearinghouse.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation drugs.com.

Decision rationale: Per drugs.com, Dicopanol is diphenhydramine hydrochloride and it was noted this drug has not been found by the FDA to be safe and effective and the labeling was not approved by the FDA. The clinical documentation submitted for review failed to provide exceptional factors to warrant non-adherence to FDA regulations. Given the above, the request for 1 prescription of Dicopanol 5 mg 150 ml is not medically necessary.

Tabradol 1mg 250ml: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Official Disability Guidelines and the National Guideline Clearinghouse.

MAXIMUS guideline: Decision based on MTUS ACOEM,Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

Decision rationale: California MTUS indicate that Cyclobenzaprine (Flexeril®) is recommended for a short course of therapy. This medication is not recommended to be used for longer than 2-3 weeks. The addition of Cyclobenzaprine to other agents is not recommended. Tabradol is a compounding kit for oral suspension of Cyclobenzaprine and Methylsulfonylmethane. A search of ACOEM, California MTUS guidelines and Official Disability Guidelines, along with the National Guideline Clearinghouse (NCG) and the PubMed database returned no discussion on Tabradol. Given the lack of evidence based literature for the oral compounding of Cyclobenzaprine and Methylsulfonylmethane over the commercially available oral forms and the lack of medical necessity requiring an oral suspension of these medications, Tabradol is not medically necessary. Given the above, the request for 1 prescription of Tabradol 1 mg 250 ml is not medically necessary.

topical Cyclophene 5% 120gm: Upheld

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

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

Decision rationale: California MTUS indicates topical analgesics are experimental in use with few randomized controlled trials to determine efficacy or safety and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. California MTUS Guidelines do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxant as there is no evidence for use of any other muscle relaxant as a topical product. The clinical documentation submitted for review failed to provide documentation of exceptional factors to warrant nonadherence to guideline recommendations. Given the above, the request for 1 prescription of topical Cyclophene 5% 120 gm is not medically necessary.

Ketoprofen cream 20% 120gm: Upheld

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

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

Decision rationale: The CA MTUS indicates topical analgesics 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. Regarding

the use of Ketoprofen: this agent is not currently FDA approved for a topical application. The clinical documentation submitted for review failed to provide documentation of exceptional factors to warrant nonadherence to guideline recommendations and additional to warrant nonadherence to FDA guidelines. Given the above, the prospective request for 1 prescription of Ketoprofen cream 20% 120 gm is not medically necessary.

1 Urine Drug Screen: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation University of Michigan Health System Guidelines for Clinical Care: Managing Chronic Non-terminal Pain, Including Prescribing Controlled Substances (May 2009), pg. 33.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Ongoing Management Page(s): 78.

Decision rationale: California MTUS indicates that the use of urine drug screening is for patients with documented issues of abuse, addiction, or poor pain control. The clinical documentation submitted for review failed to provide the patient had documented issues of abuse, addiction or poor pain control. Given the above, the request for 1 urine drug screen is not medically necessary.

9 sessions of Shockwave Therapy (6 sessions for the cervical spine and 3 sessions for the left shoulder and wrist): Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints Page(s): 203.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints Page(s): 201-205. Decision based on Non-MTUS Citation Wang, Ching-Jen. "Extracorporeal shockwave therapy in musculoskeletal disorders." Journal of orthopaedic surgery and research 7.1 (2012): 1-8.

Decision rationale: ACOEM Guidelines indicate there is medium quality evidence that supports manual physical therapy and high energy extracorporeal shockwave therapy for calcifying tendonitis of the shoulder. As there is a lack of documentation indicating the patient has calcifying tendonitis of the shoulder, the request for ESWT for the left shoulder would not be medically necessary. Per Wang, Ching-Jen (2012), "The application of extracorporeal shockwave therapy (ESWT) in musculoskeletal disorders has been around for more than a decade and is primarily used in the treatment of sports related over-use tendinopathies such as proximal plantar fasciitis of the heel, lateral epicondylitis of the elbow, calcific or non-calcific tendonitis of the shoulder and patellar tendinopathy etc." The clinical documentation submitted for review failed to provide documentation of the rationale for the extracorporeal shockwave therapy. Given the above, the prospective request for 9 Sessions of Shockwave Therapy (6 sessions for the cervical spine and 3 sessions for the left shoulder and wrist) is not medically necessary.

