

Case Number:	CM13-0064341		
Date Assigned:	01/03/2014	Date of Injury:	03/01/2013
Decision Date:	04/18/2014	UR Denial Date:	11/11/2013
Priority:	Standard	Application Received:	12/11/2013

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 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 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 48-year-old female who reported an injury on 03/01/2013. The mechanism of injury was a motor vehicle accident. The patient's medical history included Synapryn, Fanatrex, Tabradol, Deprezine, and Dicopanil since 07/2013. The recent documentation of 10/08/2013 revealed the patient had pain with heel walking, tenderness in the lumbar paraspinal muscles, quadratus lumborum, and lumbosacral junction. The patient had decreased range of motion and a positive tripod flip and Lasegue's sign. The patient had intact sensation bilaterally and decreased motor strength bilaterally to the lower extremities. The cervical spine examination revealed the patient had tenderness in the occiputs and subacromial space, paracervical trapezius, and levator scapula muscles. The patient had positive compression and distraction tests. The patient had decreased sensation bilaterally and 4/5 motor strength in the bilateral upper extremities. The patient complained of burning radicular neck pain that was constant and moderate to severe with an 8/10 VAS score; the patient complained of numbness and tingling to the bilateral upper extremities. The patient complained of burning radicular low back pain, 8/10, that was constant and moderate to severe. The patient indicated the pain traveled down the left lower extremity into the bottom of the foot and had associated numbness and tingling. The patient indicated the symptoms persisted but the medication and patches offered temporary relief of pain. The patient's diagnoses were noted to include cervical spine pain and radiculopathy, and lumbar spine pain, radiculopathy, and disc displacement, HNP. The treatment plan was noted to include medication refills, physical therapy, chiropractic care, shockwave therapy, a TENS unit, hot and cold unit, and a pain management consult.

IMR ISSUES, DECISIONS AND RATIONALES

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

Synapryn 500ml (10mg/ml): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation (ODG) Official Disability Guidelines, Co-pack drugs

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine Sulfate, Ongoing Management, , Tramadol Page(s): 50, 78, 82, 93, 94. Decision based on Non-MTUS Citation Synapryn online drug insert, FDA.gov

Decision rationale: California MTUS Guidelines recommend tramadol for pain; however, do not recommend it as a first-line oral analgesic. A thorough search of FDA.gov did not indicate there was a formulation of topical Tramadol that had been FDA approved. The approved form of Tramadol is for oral consumption. California MTUS guidelines recommend Glucosamine Sulfate for patients with moderate arthritis pain especially, knee osteoarthritis and that only one medication should be given at a time. California MTUS guidelines also indicate there should be documentation of the patient's analgesia, activities of daily living, adverse side effects and that the patient is being monitored for aberrant drug taking behavior. Synapryn per the online package insert included tramadol and glucosamine sulfate. Clinical documentation submitted for review failed to provide the necessity for an oral suspension which included tramadol and glucosamine sulfate. The clinical documentation indicated that the patient had been taking the medication for 3 months. The clinical documentation submitted for review failed to indicate the patient had a documented decrease in the VAS score with the medications and objective functional improvement. There was a lack of documentation indicating the patient was monitored for side effects and that the patient was being monitored for aberrant drug behavior. Given the above, the request for Synapryn 500 mL 10 mg per mL is not medically necessary.

Tabradol 250ml (1mg/ml):

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation (ODG) Official Disability Guidelines, Co-pack drugs

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41.

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, Tabradol is not medically necessary. The clinical documentation submitted for review failed to indicate that the patient had muscle spasms. The clinical documentation indicated that the patient had been taking the medication for 3 months. There was lack of documentation indicating the efficacy of the requested medication. Given the above, the request for Tabradol 250 mL 1 mg per mL is not medically necessary.

Fanatrex 420ml (25mg/ml): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation (ODG) Official Disability Guidelines, Co-pack drugs

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 16.

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. There was a lack of documentation of the efficacy of the medication as the patient was noted to have been on the medication for more than 3 months. Given the above, and the lack of documentation of exceptional factors to warrant non-adherence to FDA guidelines, the request for prescription for Fanatrex 420ml (25mg/ml) is not medically necessary.

Pain management consultation for lumbar ESI: Overturned

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 182.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Introduction Page(s): 1.

Decision rationale: California MTUS Guidelines indicate that upon ruling out a potentially serious condition, conservative management is provided and if the complaint persists, the physician needs to reconsider the diagnosis and decide whether specialist evidence is medically necessary. The clinical documentation submitted for review documented that the patient had intact sensation and decreased motor strength. Due to the patient's findings of decreased motor strength, the request for pain management consultation for lumbar ESI would be medically necessary.

TENS unit: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Transcutaneous electrical nerve stimulation (TENS) Page(s): 114-12.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TENS Page(s): 115, 116.

Decision rationale: California MTUS recommends a one month trial of a TENS unit as an adjunct to a program of evidence-based functional restoration for chronic neuropathic pain. Prior to the trial there must be documentation of at least three months of pain and evidence that other appropriate pain modalities have been tried (including medication) and have failed. The clinical documentation submitted for review failed to provide documentation that other appropriate pain modalities have been trialed and failed. There was a lack of documentation indicating the patient would be utilizing the TENS unit as an adjunct to a program of evidence based restoration. The request, as submitted, failed to indicate the duration for the TENS unit and whether the TENS unit was for rental or purchase. Purchase without a 30 day trial is not recommended. Given the above, the request for a TENS unit is not medically necessary.

Hot/Cold Unit: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation (ODG) Official Disability Guidelines, neck/back

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 298.

Decision rationale: ACOEM Guidelines indicate that at home local applications of cold in the first few days of acute back complaints and thereafter, there should be applications of heat or cold. The clinical documentation submitted for review failed to provide documentation of the rationale for a hot/cold unit. The request as submitted failed to indicate the duration for the hot/cold unit. Given the above and the lack of documentation, the request for hot/cold unit is not medically necessary.

Chiropractic Therapy: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Manual Therapy Page(s): 58-59.

Decision rationale: California MTUS states that manual therapy and manipulation is recommended for chronic pain if caused by musculoskeletal conditions. For the low back, therapy is recommended initially in a therapeutic trial of 6 sessions and with objective functional improvement a total of up to 18 visits over 6 to 8 weeks may be appropriate. Treatment for flare-ups requires a need for re-evaluation of prior treatment success. Treatment is not recommended for the ankle & foot, carpal tunnel syndrome, the forearm, wrist, & hand or the knee. Also, the time to produce effect is indicated as 4 to 6 treatments several studies of manipulation have looked at duration of treatment. If chiropractic treatment is going to be effective, there should be some outward sign of subjective or objective improvement within the first 6 visits. Treatment beyond 4 to 6 visits should be documented with objective improvement in function. The request as submitted failed to indicate the quantity of chiropractic therapy being requested as well as the

body part to be treated. Given the above, the request for chiropractic therapy is not medically necessary.

Physical Therapy: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation (ODG) Official Disability Guidelines- Treatment for Workers' Compensation (TWC), 5th Edition, 2007- Physical Therapy (PT)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Physical Medicine Page(s): 98-99.

Decision rationale: California MTUS states that physical medicine with passive therapy can provide short term relief during the early phases of pain treatment and are directed at controlling symptoms such as pain, inflammation and swelling and to improve the rate of healing soft tissue injuries. Treatment is recommended with a maximum of 9 to 10 visits for myalgia and myositis and 8 to 10 visits may be warranted for treatment of neuralgia, neuritis, and radiculitis. There was a lack of documentation indicating the patient's functional deficits to support the need for therapy. The request as submitted failed to indicate the quantity of physical therapy as well as the body part to be treated. Given the above, the request for physical therapy is not medically necessary.

Shockwave Therapy: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation (ODG) Official Disability Guidelines- Treatment for Workers' Compensation (TWC)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. 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: 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 indicate the rationale for the use of shockwave therapy. The request as submitted failed to indicate the quantity and body part to be treated. Given the above, the request for shockwave therapy is not medically necessary.