

Case Number:	CM13-0065362		
Date Assigned:	01/03/2014	Date of Injury:	02/27/2012
Decision Date:	04/18/2014	UR Denial Date:	12/02/2013
Priority:	Standard	Application Received:	12/13/2013

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 Management and is licensed to practice in Florida. 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 63-year-old male who reported injury on 01/02/2012. The mechanism of injury was noted to be the patient was loading material on a truck with the help of a crane. It was indicated the patient placed the material on the truck and released the crane arms, and as the patient pushed 1 of the arms, he felt a sudden pain in the low back radiating to the left lower extremity. The patient was noted to have an MRI of the lumbar spine on 10/11/2012, which revealed, at the level of L4-5, there was a 5 mm centrally and 3 mm right foraminal central disc protrusion intending the thecal sac and impinging upon the traversing L5 nerve root, more so on the right. At L3-4, there was a 2 mm disc protrusion, the spinal canal was normal in diameter, and there was mild facet arthropathy and mild narrowing of the neural foramina by a foraminal disc protrusion. At the level of L2-3, there was a broad-based disc protrusion measuring 3 mm centrally and right foraminal and 4 mm left foraminal. There was moderate facet arthropathy. There was mild central canal stenosis and a mild narrowing of the right and moderate narrowing of the left neural foramen due to a foraminal disc protrusion. At the level of L1-2, there was a 4 mm central to left disc protrusion. The spinal canal was normal in diameter and the patient had a small facet arthropathy with no significant encroachment of the right neural foramen. The patient had mild narrowing of the left foramen by a left-sided foraminal disc protrusion. The physical examination revealed the patient had pain with heel walking. The patient was able to squat approximately 10% of normal. There was tenderness to palpation with spasms at the bilateral PSIS with lumbar paraspinal muscle guarding over the spinous processes L2-5. The patient had bilateral positive straight leg raises. The patient's sensory exam to pin prick and light touch was diminished over L4-S1 dermatomes in the left lower extremity. The patient's motor strength in the bilateral lower extremities was decreased secondary to pain. The patient's deep tendon reflexes were normal and equal. The examination of 08/06/2013 revealed

the patient had complaints of burning radicular low back pain, 7/10 to 8/10, that was constant and moderate to severe. The patient indicated that the symptoms persisted but the medications offered the patient temporary relief of pain and improvement in the patient's ability to have restful sleep. The patient denied problems with the medications. The physician revealed the patient had a heel toe walk with pain and could squat 15%. The patient had tenderness to the spinous processes L2-5 bilaterally. The testing of the PSIS revealed the patient had right-sided lumbar paraspinal muscle guarding. The patient had decreased range of motion and a positive straight leg raise, as well as a Braggard's and sitting root test. The patient had diminished sensation to the bilateral lower extremities. The patient's diagnoses were noted to include lumbar spine HNP and lumbar radiculopathy. The treatment plan was noted to include an MRI of the lumbar spine, and EMG/NCV study of the bilateral lower extremities, and medication refills. The patient was noted to be on the medications being requested since 01/2013.

IMR ISSUES, DECISIONS AND RATIONALES

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

Compounded ketoprofen, 20% in PLO gel, 120grams: 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): 111,112.

Decision rationale: California MTUS indicates topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety...are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed...Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. Regarding the use of Ketoprofen: This agent is not currently FDA approved for a topical application. The guidelines do not recommend Ketoprofen and, as such, the use of the compound would not be supported. The clinical documentation submitted for review failed to indicate the patient had a trial and failure of antidepressants and anticonvulsants. The patient was noted to be on the medication for greater than six months. The efficacy of the requested medication was not provided. Given the above, the request for Compounded Ketoprofen 20% in pluronic lecithin organogel (PLO) gel, 120 grams is not medically necessary.

Topical Analgesics: 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, Topical Muscle Relaxants 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 1 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 indicate the patient had a trial and failure of antidepressants and anticonvulsants. Additionally, the patient was noted to be taking the medications for greater than six months. There was lack of documentation of the objective functional benefit received from the medication. Given the above, the request for Compounded Cyclophene, 5% in pluronic lecithin organogel (PLO) gel, 120 grams is not medically necessary.

Synapryn (tramadol hydrochloride 10 mg/ml, in oral suspension with glucosamine - compounding kit) 10 mg/1 ml oral suspension, (500 ml): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol (Ultram) Page(s): 119.

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, they 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 1 medication should be given at a time. 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. 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. The clinical documentation indicated the patient had been taking the medication for more than six months. There was lack of documentation of the patient's analgesia and activities of daily living. There was documentation the patient was being monitored for adverse side effects and aberrant drug behavior. The clinical documentation submitted for review failed to indicate documentation of exceptional factors to warrant non-adherence to guideline recommendations. Given the above, the request for Synapryn (tramadol hydrochloride 10 mg/ml, in oral suspension with glucosamine - compounding kit) 10 mg/1 ml oral suspension, 5 ml three (3) times a day (500 ml) is not medically necessary

Tabradol, 1 mg/ml suspension, (250 ml): Upheld

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

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 weeks to 3 weeks. The addition of cyclobenzaprine to other agents is not recommended. They 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. 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. The clinical documentation submitted for review failed to provide documentation of exceptional factors to warrant non-adherence to guideline recommendations. The patient was noted to be taking the medication for greater than 6 months. There was lack of documentation of the efficacy of the requested medication. Given the above, the request for Tabradol, 1 mg/ml suspension, 5 ml two to three (2-3) times a day for muscle spasms (250 ml) is not medically necessary.

Deprizine 15 mg/ml oral suspension, take 10 ml once daily for GI pain (250 ml): Upheld

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

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

Decision rationale: California MTUS Guidelines recommend 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 indicated the patient had been on the medication for greater than six months. There was lack of documentation of the efficacy of the requested medication. Additionally, there was lack of documentation indicating the patient had signs and symptoms of dyspepsia to support ongoing use of the medication. Given the above, the request for Deprizine 15 mg/ml oral suspension, take 10 ml once daily for GI pain (250 ml) is not medically necessary.

Dicopanol, diphenhydramine 5 mg/ml oral suspension, 1 ml by mouth at bedtime (150 ml): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation drugs.com

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.drugs.com/search.php?searchterm=Dicopanol>

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. The clinical documentation submitted for review indicated the patient had been taking the medication for greater than six months. There was lack of documentation of the efficacy of the requested medication, as well as the functional benefit received from the medication. Given the above, the request for Dicopanol, diphenhydramine 5 mg/ml oral suspension, 1 ml by mouth at bedtime (150 ml) is not medically necessary.

Fanatrex (gabapentin) 25 mg/ml oral suspension, 5 ml three (3) times a day (420 ml):

Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 51-52.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 16. Decision based on Non-MTUS Citation <http://www.drugs.com/search.php?searchterm=Fanatrex>

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 approved by the FDA. The patient was taking the medication for greater than six months. The efficacy of the medication was not provided. Given the above and the lack of documentation of exceptional factors to warrant non-adherence to FDA Guidelines, the request for Fanatrex (gabapentin) 25 mg/ml oral suspension, 5 ml three (3) times a day (420 ml) is not medically necessary.

Lumbar MRI (repeat): 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)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Low Back Chapter, MRI

Decision rationale: Official Disability Guidelines recommend repeat MRIs for patients who have a significant change in symptoms and/or findings suggestive of a significant pathology. Comparison from the examination of 01/2013 and 08/2013 failed to indicate the patient had findings of a significant pathology and a significant change in symptoms. Given the above, the request for Lumbar MRI (repeat) is not medically necessary.

Nerve conduction study (NCS) of the bilateral extremities (repeat): Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Low Back Chapter, NCS

Decision rationale: Official Disability Guidelines do not recommend NCS as there is minimal justification for performing nerve conduction studies when a patient is presumed to have symptoms on the basis of radiculopathy. There was a lack of documentation of the official findings of the prior EMG/NCV. The clinical documentation submitted for review failed to indicate the patient had findings of neuropathy. There was a lack of documentation indicating a rationale for both the NCV and the EMG. Given the above, the request for Nerve conduction study (NCS) of the bilateral extremities (repeat) is not medically necessary.