

Case Number:	CM14-0203792		
Date Assigned:	01/28/2015	Date of Injury:	04/25/2011
Decision Date:	03/16/2015	UR Denial Date:	11/07/2014
Priority:	Standard	Application Received:	12/05/2014

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
 State(s) of Licensure: California, Arizona
 Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 31-year-old female who reported injury on 04/25/2011. The mechanism of injury was not provided. The injured worker underwent an MRI of the cervical spine and an MRI of the lumbar spine as well as an MRI of the thoracic spine. The MRI of the lumbar spine revealed an unremarkable MRI. The thoracic spine MRI was unremarkable. The MRI of the cervical spine revealed disc desiccation at C2-3 and C3-4. There was straightening of the normal cervical lordosis which was opined to possibly reflect an element of myospasm. At C5-6, there was a focal central disc herniation causing stenosis of the spinal canal. The disc measurements in neutral were 3.0 mm, flexion 2.0 mm and extension 2.0 mm. At the level of C6-7, there was a focal central disc herniation causing stenosis of the spinal canal. The disc measurements in neutral were 2.0 mm, flexion 2.0 mm and extension 2.0 mm. Previously, the disc measurements were noted to be 1.4 mm in neutral and 1.4 mm in flexion and extension. The date of the study was 01/17/2015. The documentation of 09/30/2015 revealed the injured worker had complaints of dull achy neck pain and muscle spasms. The pain was noted to be intermittent and moderate to severe. The injured worker complained of dull mid back pain and muscle spasms rated a 7/10 described as intermediate to frequent and moderate to severe. The injured worker complained of sharp stabbing lower back pain and muscle spasms. The injured worker indicated that medications offered temporary relief of pain and improved her ability to have a restful sleep. The injured worker denied problems with medications. The objective examination revealed +2 tenderness to palpation of the suboccipitals and scalene and sternocleidomastoid muscles. There was tenderness to palpation over the spinous processes at C2 through C5. The injured worker

had decreased range of motion of the cervical spine. The injured worker had a positive cervical distraction test bilaterally. Sensation to pinwheel was intact over C5, C6, C7, C8, and T1 dermatomes in the bilateral upper extremities. The motor strength was noted to be decreased secondary to pain in the bilateral upper extremities. The deep tendon reflexes were 2+ and symmetrical in the bilateral upper extremities. The thoracic spine revealed bilateral thoracic paraspinal muscle guarding. There was tenderness to palpation over the spinous processes at T4 through T6. The injured worker had decreased range of motion of the thoracic spine. The injured worker had a positive Kemp's test. Sensation was intact to T1-T12 bilaterally. The lumbar spine examination revealed the injured worker was able to squat to approximately 15% of normal due to pain in the low back. There was hyperlordosis. There was tenderness to palpation in the bilateral PSIS. The range of motion was decreased. The straight leg raise was positive on the right at 25 degrees and on the left at 45 degrees. The Braggard's test was positive on the right. The injured worker had diminished sensation to pinwheel at the L4, L5 and S1 dermatomes in the right lower extremity. The motor strength was decreased in the bilateral lower extremities secondary to pain. Reflexes were 1+ at the left lower extremity and 2+ at the right lower extremity. The diagnoses included cervical spine sprain/strain, cervical disc displacement HNP, cervical radiculopathy, thoracic spine pain, sprain and strain and HNP, low back pain, lumbar spine HNP, compression fracture of L2, and lumbar radiculopathy. The treatment plan included the following: Periodic UA evaluation localized intense neurostimulation therapy 1 time per week for 6 weeks, an EMG/NCV of the bilateral upper and lower extremities, a pain management evaluation regarding epidural steroid injections for the lumbar spine, Terocin patches for pain relief. The physician documented that an EMG/NCV of the bilateral upper extremities was ordered to further evaluate radiculopathy versus peripheral nerve entrapment consistent with the patient's symptoms and clinical findings. The electrodiagnostic studies were noted to be indicated per the physician where the CT or MRI was equivocal and there were ongoing pain complaints arising the question whether there may be a neurologic compromise. Additionally, a request was made for Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, topical Capsaicin, Flurbiprofen, Menthol, Cyclobenzaprine, and Gabapentin. The injured worker was noted to undergo prior urine drug screens. The physician further documented the request for Dicopanol was made for the injured worker's difficulty sleeping. The request for Deprizine was made due to NSAID use. The request for Fanatrex which contains gabapentin was made for neuropathic pain. The request for Synapryn was made as it contains tramadol and glucosamine for the treatment of neuropathic fibromyalgia type pain. The request for Tabradol was made which contains cyclobenzaprine methylsulfonylmethane for muscle relaxant purposes. The documentation indicated the injured worker failed to respond to a course of nonsteroidal anti-inflammatory medications. It was further indicated methylsulfonylmethane is regarded as a dietary supplement and is regulated by the FDA; however, it has not been approved for the treatment of osteoarthritis. There was no Request for Authorization submitted for review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Synapryn 10mg/1ml oral suspension 500ml: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines recommend tramadol for pain; however, do not recommend it as a first-line oral analgesic and they recommend Glucosamine Sulfate for patients with moderate arthritis pain especially, knee osteoarthritis and that only one medication should be given at a time. Synapryn per the online package insert included tramadol and glucosamine sulfate. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. As Tramadol is a form of an opiate, the California Medical Treatment Utilization Schedule chronic pain guidelines recommend opiates for chronic pain. There should be documentation of an objective improvement in function, an objective decrease in pain, and evidence that the patient is being monitored for aberrant drug behavior and side effects. The clinical documentation submitted for review failed to indicate the injured worker had arthritis pain. The documentation indicated the injured worker was undergoing urine drug screens. There was a lack of documentation of objective functional improvement, and objective decrease in pain and that the injured worker was being monitored for side effects. The duration of use could not be established. There was a lack of documentation indicating the injured worker had a necessity for liquid versus tablet or capsules. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Synapryn 10 mg/1 ml oral suspension 500 ml is not medically necessary.

Tabradol 1mg/ml oral suspension 250ml: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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

Decision rationale: Per the physician, Tabradol is a compounding kit for oral suspension of cyclobenzaprine and methylsulfonylmethane. A search of ACOEM, California Medical Treatment Utilization Schedule guidelines and Official Disability Guidelines, along with the National Guideline Clearinghouse (NCG) and the PubMed database returned no discussion on Tabradol. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. There was a 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. The clinical documentation submitted for review failed to provide documentation to support the use of this medication. There was a lack of documentation indicating the injured worker had a condition that would allow them to swallow a tablet or capsule. There was a lack of documentation indicating a necessity for both a topical and oral form of this medication.

Additionally, the physician documented that methylsulfonylmethane is not FDA approved. The duration of use could not be established. There was a lack of documentation indicating the injured worker had a necessity for liquid versus tablet or capsules. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Tabradol 1 mg/ml oral suspension 250 ml is not medically necessary.

Deprizine 15mg/ml oral suspension 250ml: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 69. Decision based on Non-MTUS Citation Drugs.com.

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines recommends Histamine 2 blockers for treatment of dyspepsia secondary to NSAID therapy. The medication Deprizine includes ranitidine which is a Histamine 2 blocker and can be used for the treatment of dyspepsia. However, per Drugs.com, Deprizine: Generic Name: ranitidine hydrochloride has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. The clinical documentation submitted for review failed to provide documentation of exceptional factors to warrant nonadherence to guideline recommendations. There was a lack of documentation indicating the injured worker had a condition that required an H2 blocker. The duration of use could not be established. There was a lack of documentation indicating the injured worker had a necessity for liquid versus tablet or capsules. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Deprizine 15 mg/ml oral suspension 250 ml is not medically necessary.

Dicopanor (diphenhydramine) 5mg/ml oral suspension 150ml: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Insomnia Treatments and <http://www.drugs.com/search.php.searchterm=Dicopanor>.

Decision rationale: The Official Disability Guidelines indicate that sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine) and that tolerance seems to develop within a few days. Per Drugs.com, Dicopanor 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 use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. The clinical documentation submitted for review indicated the injured worker was having better sleep with medications. However, there was a lack of documentation indicating which medications were giving better sleep and a quantification of better sleep. The duration of use could not be established. There was a lack of

documentation indicating the injured worker had a necessity for liquid versus tablet or capsules. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Dicoplanol (diphenhydramine) 5 mg/ml oral suspension 150 ml is not medically necessary.

Fanatrex (gabapentin) 25mg/ml oral suspension 420 ml: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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

Decision rationale: The California Medical Treatment Utilization Schedule guidelines indicate that Gabapentin is used in the treatment of neuropathic pain. Per drugs.com, Fanatrex is an oral suspension of Gabapentin that has not approved by the FDA. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. The clinical documentation submitted for review failed to indicate the injured worker had a necessity for liquid versus tablet or capsule form of the medication. Additionally, Fanatrex is not approved by the FDA and therefore would not be supported. There was a lack of documentation indicating a necessity for both a topical and oral form of the medication. The duration of use could not be established. There was a lack of documentation indicating the injured worker had a necessity for liquid versus tablet or capsules. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Fanatrex (gabapentin) 25 mg/ml oral suspension 420 ml is not medically necessary.

UA toxicological evaluation: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opiates, steps to avoid misuse/addiction and Substance abuse (tole.

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

Decision rationale: The California Medical Treatment Utilization Schedule indicates that the use of drug screening is for patients with documented issue of abuse, addiction, or poor pain control. The clinical documentation submitted for review failed to indicate the injured worker had issues of abuse, addiction or poor pain control. There was a lack of documentation of exceptional factors to warrant the necessity for a urinalysis. The request as submitted failed to indicate the date of the request. Given the above, the request for UA toxicological evaluation is not medically necessary.

EMG/NCV of the bilateral upper extremities: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 178. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Neck and Upper Back (Acute & Chronic)

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 177-179.

Decision rationale: The American College of Occupational and Environmental Medicine states that Electromyography (EMG), and nerve conduction velocities (NCV), including H-reflex tests, may help identify subtle focal neurologic dysfunction in patients with neck or arm symptoms, or both, lasting more than three or four weeks. There should be documentation of 3 to 4 weeks of conservative care and observation. The clinical documentation submitted for review indicated the injured worker had MRI findings. However, there was a lack of documentation of a failure of conservative care and observation. The conservative care was not provided. The injured worker was noted to have a positive cervical distraction test (Spurling's test). Sensation was noted to be intact. The documentation indicated the injured worker's motor strength was decreased secondary to pain. The physician documented the request was made to evaluate radiculopathy versus peripheral nerve entrapment. However, given the lack of documentation of a failure of conservative care, this request would not be supported. Given the above, the request for EMG/NCV of the bilateral upper extremities is not medically necessary.

EMG/NCV of the bilateral lower extremities: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 303. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Low Back-Lumbar & Thoracic (Acute & Chronic)

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 303-305. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back Chapter, Nerve conduction studies (NCS).

Decision rationale: The American College of Occupational and Environmental Medicine states that Electromyography (EMG), including H reflex tests, may be useful to identify subtle, focal neurologic dysfunction in patients with low back symptoms lasting more than three or four weeks. There should be documentation of 3 to 4 weeks of conservative care and observation. The 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 is no documentation of peripheral neuropathy condition that exists in the bilateral lower extremities. There is no documentation specifically indicating the necessity for both an EMG and NCV. The clinical documentation submitted for review failed to provide documentation of a failure of conservative care. The specific conservative care was not provided. The physician indicated the justification for the request and the rationale was that the MRI was equivocal and there were ongoing complaints of pain. However, this request for a nerve conduction velocity would not be supported. Given the above and the lack of documentation of a failure of conservative care, the request for EMG/NCV of the bilateral lower extremities is not medically necessary.

Six LINT sessions for the lumbar spine: 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), Low Back-Lumbar & Thoracic (Acute & Chronic)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NMES, TENS Page(s): 121 and 114-116.

Decision rationale: The California Medical Treatment & Utilization Schedule guidelines indicate that a neuromuscular electrical stimulation (NMES devices) is not recommended. NMES is used primarily as part of a rehabilitation program following stroke and there is no evidence to support its use in chronic pain. There are no intervention trials suggesting benefit from NMES for chronic pain. A one month trial of a TENS unit is recommended if it is used 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 of 3 months of pain and evidence that other pain modalities have been trialed including medication. Additionally, there was a lack of documentation indicating exceptional factors to warrant nonadherence to guideline recommendations regarding the use of neuromuscular electrical stimulation. Given the above, the request for 6 LINT sessions for the lumbar spine is not medically necessary.

Pain management evaluation regarding epidural steroid injections for the lumbar spine: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Epidural Steroid Injections. Decision based on Non-MTUS Citation Chronic Pain Disorder Medical Treatment Guidelines, State of Colorado Department of Labor and Employment, 4/27/2007. page 56

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Epidural Steroid Injection, Ongoing management Page(s): 46 and 78.

Decision rationale: The California Medical Treatment Utilization Schedule guidelines recommend consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. The documentation submitted for review indicated the injured worker was to have a pain management evaluation for epidural steroid injections of the lumbar spine. However, the MRI failed to provide documentation of nerve impingement and as such, epidural steroid injections would not be supported. The California Medical Treatment Utilization Schedule Guidelines recommend epidural steroid injections when there is documentation of objective findings of radiculopathy upon examination that are corroborated by electrodiagnostics or imaging studies and there is documentation the injured worker has failed conservative care including exercise, physical medicine treatment, NSAIDs, and muscle relaxants. As the epidural

would not be supported, the request for a pain management evaluation is not medically necessary.

Terocin patches: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Medications and Lidocaine, topical.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals, Topical Analgesics, Lidocaine Page(s): 105, 111, and 112. Decision based on Non-MTUS Citation <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm.setid=100ceb76-8ebe-437b-a8de-37cc76ece9bb>.

Decision rationale: The California Medical Treatment Utilization Schedule guidelines indicate that topical analgesics are largely experimental in use with few randomized control 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 one drug (or drug class) that is not recommended is not recommended. The guidelines indicate that topical lidocaine (Lidoderm) 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). No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. The guidelines recommend treatment with topical salicylates. Per dailymed.nlm.nih.gov, Terocin patches are topical Lidocaine and Menthol. The clinical documentation submitted for review failed to indicate the injured worker had a trial and failure of anticonvulsants and antidepressants. There was a lack of documentation of exceptional factors to warrant nonadherence to guideline recommendations. The request as submitted failed to indicate the quantity and frequency for the requested medication as well as the body part to be treated. Given the above, the request for Terocin patches is not medically necessary.

Capsaicin: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin Page(s): 28.

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines recommend capsaicin as an option for injured workers who have not responded to or are intolerant of other treatments. The clinical documentation submitted for review failed to indicate the injured worker was not tolerant of other treatments or had not responded. The request as submitted failed to indicate the frequency, body part and quantity of capsaicin being requested. Given the above, the request for capsaicin is not medically necessary.

Flurbiprofen: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen Page(s): 72.

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines indicate that Flurbiprofen is recommended as an oral medication and is not FDA approved as a topical medication. There was a lack of documentation indicating which form of the medication was being requested. The clinical documentation submitted for review failed to provide the dosage for the requested medication. The request as submitted failed to indicate the dosage, frequency, and quantity of Flurbiprofen being requested and whether the usage was topical or oral. There was a lack of documentation of exceptional factors to support the use of this medication as a topical product. Given the above, the request for Flurbiprofen is not medically necessary.

Menthol: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals, Topical Analgesics Page(s): 105 and 111.

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines support the use of topical salicylates. However, the request as submitted failed to indicate the components to support the use of menthol. Topical analgesics are noted to be primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The clinical documentation submitted for review failed to indicate the injured worker had a trial of antidepressants and anticonvulsants. The rationale for the use of Menthol was not provided. The request failed to indicate the frequency, quantity, and the body part to be treated. Given the above and the lack of documentation, the request for menthol is not medically necessary.

Cyclobenzaprine: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Topical Muscle relaxants Page(s): 41 and 113.

Decision rationale: The California Medical Treatment Utilization Schedule 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. 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. The clinical documentation submitted for review indicated the injured worker as to utilize an oral form of the medication. There was a lack of documentation indicating a necessity for both an oral and topical form of the medication. The request as submitted failed to indicate whether the request was for topical or oral form of the medication. The request as submitted failed to indicate the frequency, quantity and strength of the requested medication. Given the above, the request for cyclobenzaprine is not medically necessary.