

Case Number:	CM15-0125918		
Date Assigned:	07/10/2015	Date of Injury:	06/24/2011
Decision Date:	09/04/2015	UR Denial Date:	06/19/2015
Priority:	Standard	Application Received:	06/30/2015

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: New York

Certification(s)/Specialty: Anesthesiology

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 51 year old female, who sustained an industrial injury on 6/24/2011. The mechanism of injury is injury from a fall. The current diagnoses are cervical spine herniated nucleus pulposus, cervical spine radiculopathy, thoracic spine pain, lumbar spine herniated nucleus pulposus, lumbar radiculopathy, internal derangement of the right knee, and lateral and medial meniscal tear of the left knee. According to the progress report dated 6/8/2015, the injured worker complains of burning, radicular neck pain with spasms. The pain is associated with numbness and tingling in the bilateral upper extremities. Additionally, she complains of burning, radicular mid and low back pain with muscles spasms. The pain is associated with numbness and tingling in the bilateral lower extremities. Also, she has bilateral burning knee pain and spasms. Her overall pain is rated 6/10 on a subjective pain scale. She states that the symptoms persist but the medications do offer her temporary relief of pain and improve her ability to have a restful sleep. The physical examination of the cervical spine reveals tenderness to palpation over the paraspinal, occiput, trapezius, and scalene muscles, limited range of motion, positive Spurling's and compression tests bilaterally, decreased motor strength bilaterally secondary to pain, and diminished sensation to pinprick and light touch over C5, C6, C7, C8, and T1 dermatomes in the bilateral upper extremities. Examination of the thoracolumbar spine reveals tenderness to palpation with spasms over the bilateral paraspinal muscles, quadratus lumborum muscles, and sacroiliac joints, restricted range of motion, decreased motor strength bilaterally due to pain, diminished sensation to pinprick and light touch over the L4, L5, and S1 dermatomes in the bilateral lower extremities, and positive flip, straight leg raise, sitting root,

and Kemp's test bilaterally. The bilateral knee exam reveals patellofemoral crepitus with range of motion, +1 effusion, tenderness to palpation over the medial and lateral joint line bilaterally, reduced range of motion, and positive McMurray's and Apley's compression test bilaterally. The current medications are Synapryn, Tabradol, Deprizine, Dicopanol, Fanatrex, and topical compound cream. There is documentation of ongoing treatment with these medications since at least 2/2/2015. Treatment to date has included medication management, x-rays, physical therapy, hot packs, massage, MRI studies, electrodiagnostic testing, and epidural steroid injections. Work status was deferred to the primary treating physician, and could not be identified. A request for Synapryn, Tabradol, Deprizine, Dicopanol, Fanatrex, Ketoprofen cream, and Cyclobenzaprine cream has been submitted.

IMR ISSUES, DECISIONS AND RATIONALES

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

Synapryn 10mg/ml oral suspension 500ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioid use for chronic pain. Decision based on Non-MTUS Citation
<http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=594bad96-d0e0-4a12-8a38-762962f54a66>.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioid Page(s): 74-96, 113.

Decision rationale: According to the California MTUS, Synapryn oral suspension (Tramadol hydrochloride with glucosamine) contains a synthetic opioid which affects the central nervous system and is indicated for the treatment of moderate to severe pain. Per CA MTUS Guidelines, certain criteria need to be followed, including an ongoing review and documentation of pain relief and functional status, appropriate medication use, and side effects. Pain assessment should include current pain: last reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid, and the duration of pain relief. According to the medical records, there has been no documentation of the medication's analgesic effectiveness or functional improvement, and no clear documentation that the patient has responded to ongoing opioid therapy. An oral suspension is a suspension consisting of un-dissolved particles of one or more medicinal agents mixed with a liquid vehicle for oral administration. Evidence-based guidelines and peer-reviewed medical literature do not address the use of medications in oral suspension form. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. In this case, the treating physician did not document the least reported pain over the period since last assessment, average pain, and intensity of pain after taking the opioid, how long it takes for pain relief, how long pain relief lasts, improvement in pain, and improvement in function. These are necessary to meet the CA MTUS guidelines. In addition, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result. Therefore, based on CA MTUS guidelines and submitted medical records, the request for Synapryn is not medically necessary.

Tabradol 1mg/ml oral suspension 250ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain procedure - Muscle relaxants (for pain)<http://www.drugs.com/cons/fusepaq-tabradol.html>.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63-64.

Decision rationale: The CA MTUS Chronic Pain Medical Treatment Guidelines recommend muscle relaxants be used as an option, using a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. Treatment should be brief. Furthermore, muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. In this case, the guidelines recommend muscle relaxants only for a short duration, and not longer than 2-3 weeks. There is documentation of ongoing treatment with Tabradol since at least February 2015. In addition, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result. Therefore, based on CA MTUS guidelines and submitted medical records, the request for Tabradol is not medically necessary.

Deprizine 15mg/ml oral suspension 250ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MD Consult Drug Monograph - <http://www.drugs.com/pro/deprizine.html>.

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

Decision rationale: Deprizine (Ranitidine) oral suspension is a histamine blocker and antacid used to treat peptic ulcers, gastritis and gastro-esophageal reflux (GERD). Ranitidine works by blocking the effects of histamine on the receptor site known as H2. Proton Pump Inhibitors (PPI's) are prescribed to prevent and treat ulcers in the duodenum (where most ulcers develop) and the stomach. Deprizine oral suspension is a suspension consisting of un-dissolved particles of one or more medicinal agents mixed with a liquid vehicle for oral administration. In this case, there is no documentation to support the injured worker had a gastrointestinal disorder, peptic ulcer or gastroesophageal reflux disease. Medical necessity of the Deprizine (Ranitidine) oral suspension has not been established. The requested medication is not medically necessary.

Dicopanol (Diphenhydramine) 5mg/ml oral suspension 150ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MD Consult - <http://www.drugs.com/pro/dicopanol.html>.

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

Decision rationale: The CA MTUS is silent regarding the use of Dicopanol. However, according to the progress notes, Dicopanol is a compound medication that contains diphenhydramine and other unknown proprietary ingredients. Per the Official Disability Guidelines (ODG), Diphenhydramine is a sedating antihistamine which is not recommended for long-term insomnia treatment. In this case, the submitted medical records failed to provide documentation regarding sleep history or diagnosis that would support the use of Dicopanol. In addition, guidelines do not recommend Dicopanol for long-term insomnia treatment. Whereas, the records indicate that there has been ongoing treatment with Dicopanol since at least 2/2/2015. Therefore, based on the ODG and submitted medical records, the request for Dicopanol is not medically necessary.

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

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs). Decision based on Non-MTUS Citation <http://www.drugs.com/pro/fanatrex.html>.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs) Page(s): 16-19, 49.

Decision rationale: Per the CA MTUS Chronic Pain Medical Treatment Guidelines, Fanatrex (Gabapentin) is an anti-epilepsy drug (AEDs - also referred to as anti-convulsants), which has been shown to be effective for treatment of diabetic painful neuropathy and post herpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. According to the progress notes, Fanatrex is a compound medication that contains Gabapentin and other proprietary ingredients including glucosamine. In this case, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result. Therefore, based on CA MTUS guidelines and submitted medical records, the request for Fanatrex is not medically necessary.

Ketoprofen 20% cream 165 grams: 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): 111-113.

Decision rationale: According to the CA MTUS guidelines topical analgesics are recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants (AEDs) have failed. 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. Furthermore, Ketoprofen agent is not currently FDA approved for a topical application. In this case, there is no documentation that the injured worker has failed a trial of antidepressants or AEDs to support the use of topical analgesics as required by the CA MTUS. Based on the MTUS guidelines and submitted medical records, the request for Ketoprofen cream is not medically necessary.

Cyclobenzaprine 5% cream 100grams: 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): 111-113.

Decision rationale: According to the CA MTUS Chronic Pain Medical Treatment Guidelines topical analgesics are recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. 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. Furthermore, the guidelines suggest there is no evidence for use of Cyclobenzaprine as a topical product. In this case, there is no documentation that the injured worker has failed a trial of oral antiepileptic and antidepressant medications to support the use of topical analgesics as required by the CA MTUS. In addition, do not support the use of Cyclobenzaprine as a topical product. Therefore, based on MTUS guidelines and submitted medical records, the request for Cyclobenzaprine cream is not medically necessary.