

Case Number:	CM15-0060266		
Date Assigned:	04/17/2015	Date of Injury:	12/08/2013
Decision Date:	07/15/2015	UR Denial Date:	03/02/2015
Priority:	Standard	Application Received:	03/30/2015

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: Pennsylvania
Certification(s)/Specialty: Internal Medicine

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 63-year-old female who sustained an industrial injury on December 8, 2013. The injured worker was diagnosed as having cervical spine pain, cervical spine sprain/strain, wrist pain, thoracic spine sprain/strain, thoracic spine pain, low back pain, lumbar spine sprain/strain, lower extremity radiculitis, lumbar spine degenerative disc disease, lumbar disc displacement/herniated nucleus pulposus (HNP), right knee sprain/strain, right knee lateral meniscal tear, right knee internal derangement, right knee Baker's cyst, and right foot osteoarthritis. Treatment and evaluation to date has included localized intense neurostimulation therapy, shockwave therapy, acupuncture, MRIs, and medication. Deprizine, dicopanol, fanatrex, synapryn, trabadol (which contains cyclobenzaprine and methylsulfonylmethane), cyclobenzaprine, and ketoprofen cream were prescribed since September of 2014. Currently, the injured worker complains of burning radicular neck pain, burning bilateral wrist pain and muscle spasm, burning radicular mid back pain and muscle spasm, burning low back pain associated with numbness and tingling of the bilateral lower extremities, burning right knee pain, and burning right foot pain. The Primary Treating Physician's report dated January 20, 2015, noted the injured worker reported her symptoms persisted but medications offered temporary relief of pain and improved ability to have restful sleep. Physical examination was noted to show tenderness to palpation at the cervical paraspinal muscles, tenderness at the bilateral wrists carpal tunnel, and sensation to pinprick and light touch was slightly diminished over the C5, C6, C7, C8, and T1 dermatomes in the bilateral upper extremities. The thoracic spine was noted to have palpable tenderness over the bilateral thoracic paraspinals. Two plus tenderness to palpation at the lumbar paraspinal muscles and over the lumbosacral junction was noted. Tenderness to palpation over the medial and lateral joint lines and to the bilateral knee patella-femoral joint, tenderness to palpation at the right foot dorsal aspect, and tenderness at the right

foot calcaneus were also noted. Sensory exam was noted to show slightly decreased sensation to pinprick and light touch at the L4, L5, and S1 dermatomes in the right lower extremity. Work status was temporarily totally disabled from September 2014 through February 2015. The treatment plan was noted to include a referral to pain management, referral to an orthopedic surgeon, chiropractic treatments, localized intense neurostimulation therapy, Terocin patches, and continued medications including Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Cyclobenzaprine, and Ketoprofen cream. On 3/2/14, Utilization Review (UR) non-certified requests for the items currently under Independent Medical Review, citing the MTUS and ODG.

IMR ISSUES, DECISIONS AND RATIONALES

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

Chiropractic 1x week x 6 weeks for the Lumbar Spine: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Manual therapy & manipulation Page(s): 58-59.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines manual therapy and manipulation Page(s): 58-60.

Decision rationale: Per the MTUS for Chronic Pain, the purpose of manual medicine is functional improvement, progression in a therapeutic exercise program, and return to productive activities (including work). Per the MTUS for Chronic Pain, a trial of 6 visits of manual therapy and manipulation may be provided over 2 weeks, with any further manual therapy contingent upon functional improvement. Per the MTUS, chiropractic manipulation is not recommended for the "Ankle & Foot, Carpal tunnel syndrome, Forearm, Wrist, & Hand, Knee." This injured worker has chronic back pain. No prior chiropractic treatment was discussed, and as such, this request is consistent with an initial request for chiropractic treatment. The Utilization Review determination stated that the number of completed sessions is not specified in the medical records to determine medical necessity, and that there was no documentation of functional improvement with previous treatments. However, there was no indication that this injured worker had undergone any prior chiropractic treatment. The number of sessions requested (6) is consistent with the guideline recommendations for an initial trial. As such, the request for chiropractic treatment is medically necessary.

Ketoprofen 20% cream 167 grams apply thin later to affected area TID: 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 topical analgesics Page(s): 111-113.

Decision rationale: Ketoprofen, a non-steroidal anti-inflammatory agent (NSAID), is not currently FDA approved for topical application. It has a high incidence of photo contact dermatitis. Topical NSAIDS are indicated for osteoarthritis and tendinitis, in particular that of the knee and elbow or other joints that are amenable to topical treatment. This injured worker has chronic back pain. There is little evidence to utilize topical NSAIDS for treatment of osteoarthritis of the spine, hip, or shoulder, and topical NSAIDS are not recommended for neuropathic pain. As topical ketoprofen is not FDA approved, it is therefore experimental and cannot be presumed as safe and efficacious. Non-FDA approved medications are not medically necessary. As such, the request for ketoprofen cream is not medically necessary.

Cyclobenzaprine 5% cream 110grams apply thin layer to affected area TID: 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 topical analgesics Page(s): 111-113.

Decision rationale: Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There was no documentation of trial and failure of antidepressant or anticonvulsant medication. Cyclobenzaprine is a muscle relaxant. The MTUS notes that there is no evidence for use of muscle relaxants as topical products. The treating physician has prescribed both oral and topical cyclobenzaprine, which is duplicative and potentially toxic. Due to lack of recommendation by the guidelines for the use of topical muscle relaxants, the request for cyclobenzaprine cream is not medically necessary.

Synapryn 10mg/1ml oral suspension 500ml 1 tsp(5ml) TID: 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 opioids p. 77-80, 93-94, glucosamine (and chondroitin sulfate) p. 50 Page(s): 77-80, 93-94, 50.

Decision rationale: Synapryn contains tramadol with glucosamine in oral suspension. The reason for combining these medications is not discussed in any physician report. Given that tramadol is generally an as-needed medication to be used as little as possible, and that glucosamine (assuming a valid indication) is to be taken regularly regardless of acute symptoms, the combination product is illogical and not indicated. Tramadol is prescribed without clear evidence of the considerations and expectations found in the MTUS and similar guidelines. Opioids are minimally indicated, if at all, for chronic back pain. The prescribing physician does not specifically address function with respect to prescribing opioids, and does not address the other recommendations in the MTUS. There is no evidence that the treating physician has utilized a treatment plan NOT using opioids, and that the patient "has failed a trial of non-opioid analgesics." The MTUS provides support for treating moderate arthritis pain, particularly knee OA, with glucosamine sulphate. Other forms of glucosamine are not supported by good medical

evidence. The treating physician in this case has not provided evidence of the form of glucosamine in Synapryn, and that it is the form recommended in the MTUS and supported by the best medical evidence. Should there be any indication for glucosamine in this case, it must be given as a single agent apart from other analgesics, particularly analgesics like tramadol that are habituating. Synapryn is not medically necessary based on the MTUS, lack of good medical evidence, and lack of a treatment plan for chronic opioid therapy consistent with the MTUS.

Tabradol 1mg/ml oral suspension 20ml 1 tsp(5ml) 2-3 times a day: 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 p. 41-42 muscle relaxants p. 63-66 Page(s): 41-42, 63-66.

Decision rationale: This injured worker has chronic neck and back pain. Trabadol (Cyclobenzaprine) has been prescribed for at least five months. Tabradol is cyclobenzaprine in an oral suspension. The MTUS for chronic pain does not recommend muscle relaxants for chronic pain. Non-sedating muscle relaxants are an option for short-term exacerbations of chronic low back pain. The muscle relaxant prescribed in this case is sedating. The injured worker has chronic pain with no evidence of prescribing for flare-ups. No reports show any specific and significant improvement in pain or function as a result of prescribing muscle relaxants. Per the MTUS chronic pain medical treatment guidelines, cyclobenzaprine (Flexeril, Fexmid, Amrix, Trabadol) is a skeletal muscle relaxant and a central nervous system depressant. It is recommended as an option for a short course of therapy, with greatest effect in the first four days of treatment. Guidelines state that treatment should be brief. Cyclobenzaprine is not recommended to be used for longer than 2-3 weeks. The addition of cyclobenzaprine to other agents is not recommended. This injured worker has been prescribed multiple additional agents. Limited, mixed evidence does not allow for a recommendation for chronic use. The treating physician has prescribed both oral and topical cyclobenzaprine, which is duplicative and potentially toxic. Due to length of use in excess of the guideline recommendations, and potential for toxicity, the request for trabadol is not medically necessary.

Deprizine 15 mg per ml oral suspension 250ml 2 tsp (10 ml): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI symptoms and cardiovascular risk Page(s): 68-69.

Decision rationale: The MTUS recommends co-therapy of non-steroidal anti-inflammatory agents (NSAIDs) with a proton pump inhibitor (PPI) in patients who are determined to be at intermediate or high risk of a gastrointestinal (GI) event. There is no recommendation for histamine -2 (H2) receptor antagonists for gastric protection from NSAID use. A H2-receptor antagonist may be considered for treatment of dyspepsia secondary to NSAID therapy. Deprizine

is ranitidine in an oral suspension. Ranitidine is prescribed without any rationale provided. If ranitidine is prescribed as cotherapy with an NSAID, ranitidine is not the best drug. Note the MTUS recommendations cited. There are no medical reports, which describe signs and symptoms of possible gastrointestinal (GI) disease. There is no examination of the abdomen on record. No reports describe the specific risk factors present in this case. Due to lack of specific indication, the request for deprezine is not medically necessary.

Dicopanол (Diphenhydramine) 5mg pre ml oral suspension 150ml 1 ml PO at bedtime:
Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Pain (updated 02/23/15) Insomnia treatment.

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.

Decision rationale: Dicopanол contains diphenhydramine and other unnamed ingredients. Medical necessity cannot be determined for unspecified compounds, and unpublished ingredients cannot be assumed to be safe or effective. Dicopanол is not medically necessary on this basis alone. In addition, Dicopanол is stated to be for insomnia. The MTUS does not address the use of hypnotics other than benzodiazepines. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. Note the Official Disability Guidelines citation above. That citation also states that antihistamines are not indicated for long term use as tolerance develops quickly, and that there are many, significant side effects. Dicopanол is not medically necessary based on lack of a sufficient analysis of the patient's condition, the ODG citation, and lack of information provided about the ingredients.

Fanatrex (Gabapentin) 25mg per ml oral suspension 420ml 1 tsp (5 ml) TID: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines anticonvulsants Page(s): 16-22.

Decision rationale: Fanatrex is a formulation of gabapentin in oral suspension. Fanatrex has been prescribed for this injured worker for at least five months. Per the MTUS, anti-epilepsy drugs (AEDs) are recommended for neuropathic pain due to nerve damage. Gabapentin (Neurontin) has been shown to be effective for treatment of diabetic neuropathy and post herpetic neuralgia and has been considered a first line treatment for neuropathic pain. The MTUS notes the lack of evidence for treatment of radiculopathy (the apparent reason for the prescription per the treating physician). A "good" response to the use of AEDs is defined as a 50% reduction in pain and a "moderate" response as a 30% reduction. Lack of at least a 30% response per the

MTUS would warrant a switch to a different first line agent or combination therapy. After initiation of treatment, there should be documentation of pain relief with improvement in function, and documentation of any side effects, with continued use of AEDs dependent on improved outcomes versus tolerability of adverse effects. In this case, there was no documentation of significant improvement in pain or function because of use of fanatrex. Work status remained temporarily very disabled, and there was no discussion of improvement in activities of daily living or reduction in medication use. Due to lack of significant improvement in pain or function, the request for fanatrex is not medically necessary.