MAXIMUS Federal Services

Case Number:	CM15-0113135		
Date Assigned:	06/24/2015	Date of Injury:	03/17/2014
Decision Date:	08/04/2015	UR Denial Date:	05/12/2015
Priority:	Standard	Application Received:	06/11/2015

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: Emergency 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 68 year old female who sustained an industrial injury on 03/17/2014 resulting in pain/injury to the mid and low back, left hip and left leg after being attacked by 2 men. The initial diagnoses included back pain, lumbar muscle strain, thoracic muscle strain and adult physical abuse. Treatment provided to date has included: physical therapy for the thoracic and lumbar spines (18 sessions), chiropractic treatments (6), medications, and conservative therapies/care. Diagnostic tests performed include: nerve conduction studies of the lower extremities suggestive of right peroneal neuropathy; and x-rays of the thoracic and lumbar spines (07/17/2014) showing grade II degenerative anterolisthesis of L4-5, degenerative disc height in the lumbar spine, restricted range of motion in the lumbar spine, levoconvex scoliosis of the thoracic and lumbar spines, and degenerative anterior superior and anterior inferior, right lateral and left lateral endplate osteophytes. Co-morbidities included hay fever, gout, high blood pressure, and hyperthyroidism. There were no other dates of injury noted. On 04/08/2015, physician progress report noted complaints of mid back pain. The pain was rated 6/10 (0-10) in severity, and was described as constant, burning, moderated to severe, and aggravated by prolonged walking, standing, sitting and bending. Additional complaints included low back pain that was rated 7-8/10 and described as constant, moderate to severe, radiating to the left lower extremity with associated numbness and tingling in the left lower extremity, and aggravated by prolonged sitting, standing, walking, bending, arising from the sitting position, ascending/ descending stairs and stooping; and left thigh pain which was rated 7/10 in severity, associated with numbness and tingling in the thigh, and aggravated by any squatting, kneeling,

ascending/descending stairs, arising from the seated position, prolonged weight bearing, standing, and walking. Previous pain ratings were noted as: 5-6/10 on 01/05/2015; 6-7/10 on 02/23/2015; 7-8/10 on 03/11/2015; and 7/10 on 04/01/2015. Current medications include Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Capsaicin, Flurbiprofen, menthol, cyclobenzaprine and gabapentin. The clinical notes indicate that the injured worker has been taking these medications for at least 6 months. The physical exam revealed tenderness to palpation (TTP) over the trapezius muscles, restricted range of motion (ROM) in the thoracic spine, painful heel-to-toe walking, TTP of the quadratus lumborum and lumbosacral junction, TTP at the left PSISs with trigger points noted, restricted lumbar ROM, mildly positive Flip test bilaterally, TTP along the anterior thigh of the left leg, decreased sensation along the course of the lateral cutaneous femoral nerve in the left lower extremity, and slightly decreased muscle strength in the left lower extremity. The provider noted diagnoses of thoracic spine strain/sprain, low back pain, lumbar spine strain/sprain, lumbar spine radiculopathy, left thigh pain, and left thigh numbness. Plan of care includes continued medications (Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Capsaicin, Flurbiprofen, menthol, cyclobenzaprine and gabapentin), Terocin patches, physical therapy and chiropractic manipulation for the thoracic and lumbar spines, and follow-up. The injured worker's work status has been noted as working full duty at the same place of employment throughout the documentation and remains as working full duty on 04/08/2015.

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: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 91-94.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine; and Opioids Page(s): 50, 88.

Decision rationale: Synapryn is a compounded medication that contains tramadol (opioid) and glucosamine. MTUS discourages long term usage of opioids unless there is evidence of "ongoing review and documentation of pain relief, improvement in functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The MTUS recommends Glucosamine for the treatment of moderate arthritis pain (particularly in the knee). The treating physician does not document: 1) the least reported pain over the period since last assessment; 2) average pain; 3) intensity of pain after taking the opioid; 4) how long it takes for pain relief; 5) how long pain relief lasts; 6) improvement in pain; 7) improvement in function. There is also no diagnosis of arthritis, and no clinical reason for oral suspension provided in the clinical notes. These are necessary to meet MTUS guidelines. As such, the request for Synapryn 10mg/1ml oral suspension 500ml is not medically necessary.

Tabradol 1mg/ml 250ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril) Page(s): 41-42.

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

Decision rationale: Tabradol (brand names: Amrix, Flexeril and Fexmid) is an oral suspension of a centrally acting skeletal muscle relaxant. The CA MTUS recommends prescribing non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP (low back pain) as they can reduce pain from muscle tension and possibly increase mobility. However, in most cases involving LBP, they provide no more benefit beyond NSAIDs in pain and overall improvement. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Cyclobenzaprine (Amrix, Flexeril, Fexmid and other generic forms) is recommended for a short course of treatment (with greatest effect within the first 4 days) and not recommended for long term use. The clinical notes show that the injured worker has been prescribed Tabradol since 03/11/2015 with no evidence of reduction in pain or improvement in function. There was also an additional request for cyclobenzaprine, a tablet form of the same medication, submitted with this reqeust. In addition, the CA MTUS does not recommend or support the long-term use of muscle relaxants. Therefore, the request for Tabradol is not medically necessary.

Deprizine 15mg/ml 250ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68.

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

Decision rationale: Deprizine is is the oral solution equivalent of ranitidine. According to CA MTUS, gastrointestinal protectant agents are recommended for patients that are at increased risk for gastrointestinal events. These risks include age >65, history or gastrointestinal bleeding or peptic ulcers, concomitant use of NSAIDs and corticosteroids or aspirin, or high dose NSAID use. The chart does document the ongoing use of NSAIDs, but it does not report any gastrointestinal side effects. Past medical history does not include any gastrointestinal disorders, there is no history of poor tolerance to NSAIDs documented and there are not abdominal examinations noted in the chart. Based on the submitted documentation, deprizine is not medically necessary based on the CA MTUS.

Dicopanol 5mg/ml 150ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.nlm.nih.gov.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.drugs.com/pro/dicopanol.html.

Decision rationale: CA MTUS and ODG are silent on this medication. Dicopanol is a combination of antihistamine and other proprietary ingredients. Unknown components of a medication cannot be evaluated to determine their safety or medical necessity. It is unclear from the submitted documentation what this medication is intended to treat. As such, the request for Dicopanol is not medically necessary.

Fanatrex (Gabapentin) 25mg/ml 420ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy Drugs; Gabapentin Page(s): 18, 49. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (chronic), Medications, Compounded Medications and Other Medical Treatment Guidelines http://www.drugs.com/pro/fanatrex.html.

Decision rationale: Per the MTUS, Fanatrex (gabapentin) is a compounded form of an anti-epilepsy drug (AEDs - also referred to as anti-convulsants). These drugs have been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. The ODG states that compounded drugs are not recommended as first-line therapy. FDA-approved drugs should be given adequate trial, if these are inadequate, ineffective or contraindicated in the individual patient, then compounded drugs with FDA-approved ingredients can be considered. The clinical documentation submitted for review does not indicate diagnoses of diabetic neuropathy or postherpetic neuralgia. Painful neuropathic symptoms were noted; however, there is no indication for the compounded oral suspension form of this drug in such a low dose (non-therapeutic dose) in comparison to the recommended dose of oral gabapentin in tablet form. In addition, there is no documented failed trial of the FDA-approved form of this drug, and no indication as to the reason that the FDA-approved form is contraindicated in the injured worker. As such, the request for Fanatrex (gabapentin) 25mg/ml 420ml is not medically necessary.

Terocine patches: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: Per the MTUS, Fanatrex (gabapentin) is a compounded form of an anti-epilepsy drug (AEDs - also referred to as anti-convulsants). These drugs have been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been

considered as a first-line treatment for neuropathic pain. The ODG states that compounded drugs are not recommended as first-line therapy. FDA-approved drugs should be given adequate trial, if these are inadequate, ineffective or contraindicated in the individual patient, then compounded drugs with FDA-approved ingredients can be considered. The clinical documentation submitted for review does not indicate diagnoses of diabetic neuropathy or postherpetic neuralgia. Painful neuropathic symptoms were noted; however, there is no indication for the compounded oral suspension form of this drug in such a low dose (non-therapeutic dose) in comparison to the recommended dose of oral gabapentin in tablet form. In addition, there is no documented failed trial of the FDA-approved form of this drug, and no indication as to the reason that the FDA-approved form is contraindicated in the injured worker. As such, the request for Fanatrex (gabapentin) 25mg/ml 420ml is not medically necessary.

Capsaicin: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Formulations: Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. After review of the clinical notes and the request for authorization, it was noted that the specific formulation was not indicated. Terocin patches, which contains capsaicin 0.025%, has been approved. The request for capsaicin in amounts greater than 0.025% are not medically necessary. Therefore, the request for capsaicin is not medically necessary.

Flurbiprofen: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 69, 72.

Decision rationale: According to the MTUS, Flurbiprofen is recommended for mild to moderate osteoarthritis pain with a maximus daily dose of 300mg. The MTUS also states "All NSAIDs have the potential to raise blood pressure in susceptible patients. The greatest risk appears to occur in patients taking the following anti-hypertensive therapy: angiotensin-converting enzyme (ACE) inhibitors; angiotensin receptor blockers; beta blockers; or diuretics. In addition congestive heart failure may develop due to fluid retention". The clinical notes and the request for authorization failed to specify the form and dosage of this medication. It is also

noted in the clinical notes that the injured worker has hypertension and is currently taking medication for the treatment of hypertension; however, the specific medication(s) and dosing was not provided (which could be a potential contraindication). Documentation supports the IW has been taking NSAIDs for several months. The documentation does not support improvement in pain level related to this medication. Without the supporting documentation, flurbiprofen is not medically necessary at this time.

Menthol: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Char Format

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: Menthol is a component in many topical analgesics frequently used for pain and aches. According to the MTUS guidelines, "topical Analgesic are largely experimental in use with few randomized controlled trials to determine efficacy or safety. 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." Terocin patches, which contains menthol, has been approved. There is no clinical indication or evidence to support additional amounts of topical menthol. As a result, topical menthol is not medically necessary.

Cyclobenzaprine: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 41, 64.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain), and Topical Analgesics Page(s): 63-64, 113.

Decision rationale: Cyclobenzaprine (brand names: Amrix, Flexeril and Fexmid; generic form: tabradol) is a centrally acting skeletal muscle relaxant. The CA MTUS recommends non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain (LBP) as they can reduce pain from muscle tension and possibly increase mobility. However, in most cases involving LBP, they provide no more benefit beyond NSAIDs in pain and overall improvement. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Cyclobenzaprine (Amrix, Flexeril, Fexmid and other generic forms) is recommended for a short course of treatment (with greatest effect within the first 4 days) and not recommended for long term use. According to the MTUS guidelines: Topical Analgesic are largely experimental in use with few randomized controlled trials to determine efficacy or safety. 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. Topical cyclobenzaprine (a muscle relaxant) is not recommended for use as a topical agent. The clinical notes and the utilization review letter lend no insight to the requested form of this drug; therefore it is reviewed as an oral agent and in topical form. The clinical notes show that the injured worker has been prescribed topical cyclobenzaprine since 12/15/2014, and an oral form (tabradol) since 03/11/2015, with no evidence of reduction in pain or improvement in function. The CA MTUS does not recommend or support the long-term use of muscle relaxants. In addition, this drug and drug class is not recommended for topical use. Therefore, cyclobenzaprine (form and dose not specified) is not medically necessary.

Gabapentin: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 18-19.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: Cyclobenzaprine (brand names: Amrix, Flexeril and Fexmid; generic form: tabradol) is a centrally acting skeletal muscle relaxant. The CA MTUS recommends non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain (LBP) as they can reduce pain from muscle tension and possibly increase mobility. However, in most cases involving LBP, they provide no more benefit beyond NSAIDs in pain and overall improvement. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Cyclobenzaprine (Amrix, Flexeril, Fexmid and other generic forms) is recommended for a short course of treatment (with greatest effect within the first 4 days) and not recommended for long term use. According to the MTUS guidelines: Topical Analgesic are largely experimental in use with few randomized controlled trials to determine efficacy or safety. 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. Topical cyclobenzaprine (a muscle relaxant) is not recommended for use as a topical agent. The clinical notes and the utilization review letter lend no insight to the requested form of this drug; therefore it is reviewed as an oral agent and in topical form. The clinical notes show that the injured worker has been prescribed topical cyclobenzaprine since 12/15/2014, and an oral form (tabradol) since 03/11/2015, with no evidence of reduction in pain or improvement in function. The CA MTUS does not recommend or support the long-term use of muscle relaxants. In addition, this drug and drug class is not recommended for topical use. Therefore, cyclobenzaprine (form and dose not specified) is not medically necessary.

Physical therapy for the T/S, L/S and left thigh, 18 sessions: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 98.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 2 General Approach to Initial Assessment and Documentation, Chapter 12 Low Back Complaints Page(s): 299, Chronic Pain Treatment Guidelines Physical Medicine Page(s): 9, 98-99.

Decision rationale: Per the CA MTUS ACOEM guideline citation above, physical therapy recommendations apply to acute and sub-acute conditions until pain transitions to "chronic" according to the MTUS definition, and if the chapter specific treatment algorithms have been completed. However, if recovery has not taken place with the respect to pain by the end of the treatment algorithms, then the chronic pain medical treatment guidelines will apply. Per the CA MTUS guidelines, all therapies are focused on the goal of functional restoration rather than merely the elimination of pain and assessment of treatment efficacy is accomplished by reporting functional improvement. Active physical therapy is recommended for "restoring flexibility, strength, endurance, function, range of motion and can alleviate discomfort" Active physical therapy may require supervision from a therapist or medical provider such as verbal, visual or tactile instructions. Patients are instructed and expected to continue active therapies at home as an extension of the treatment process in order to maintain improvement. Physical therapy guidelines allow for fading of treatment frequency from 3 visits per week to 1 visit per week, with a maximum number of allowed visits of 8/10 visits over 4 weeks. The injured worker has previously received 18 sessions of physical therapy for the mid and low back and left lower extremity. This is in excess of the guideline's recommendations. The therapy notes were not provided for review and there was little discussion regarding the success of the physical therapy treatments. It was noted on the progress report dated 02/23/2015 that the injured worker had plateaued with physiotherapy and chiropractic therapy; however, no other details were mentioned regarding physical therapy progress. At the time of the request for additional physical therapy, the injured worker was reported to be working full time without restrictions and there was no indication that the injured worker was unable to participate in activities of daily living. There was not discussion of an ongoing home exercise program. Considering that the injured worker had previously received 18 session of physical therapy, was not showing inability for function in activities of daily living and was working full duty, it is determined that 18 additional sessions of physical therapy are not medically necessary.

Chiropractic manipulation for the T/S, L/S and left thigh, 18 sessions: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 58. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Knee and Leg-Manipulation.

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

Decision rationale: Per the CA MTUS, manual therapy/manipulation is recommended for chronic pain if caused by musculoskeletal conditions. Manual Therapy "is widely used in the treatment of musculoskeletal pain. The intended goal or effect of Manual Medicine is the achievement of positive symptomatic or objective measurable gains in functional improvement that facilitate progression in the patient's therapeutic exercise program and return to productive activities. Manipulation is manual therapy that moves a joint beyond the physiologic range-of-

motion but not beyond the anatomic range-of-motion." The MTUS recommends a trial of 6 visit of 2 weeks for the low back, and with evidence of objective functional improvement up to 18 visits over 6-8 weeks. Elective or maintenance care is not medically necessary, recurrences or flare-ups require re-evaluation of treatment success, and if return-to-work has been achieved then 1-2 visits every 4-6 months are recommended. After review of the medical documentation submitted, it was determined that there was a request for 6 sessions of chiropractic manipulation on 01/05/2015; however, it is not known how many of these were approved or completed and there were no chiropractic notes submitted. In addition, there was no evidence of functional improvement from treatment as the injured worker was working full duty at the time of the initial request for authorization for chiropractic manipulation (01/05/2015). Finally, the request for 18 visits in addition to the previously requested 6 visits exceeds the guideline recommendations for manual therapy. Therefore, the request for 18 additional chiropractic manipulation sessions is not medically necessary.