

Case Number:	CM15-0116520		
Date Assigned:	06/24/2015	Date of Injury:	09/18/2013
Decision Date:	09/22/2015	UR Denial Date:	05/27/2015
Priority:	Standard	Application Received:	06/16/2015

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: California

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 49 year old male, who sustained an industrial injury on September 18, 2013. Treatment to date has included medications. Currently, the injured worker complains of low back pain which he describes as moderate to severe constant burning. The pain is associated with numbness and tingling of the bilateral lower extremities. The pain is aggravated with prolonged sitting, standing, bending, walking and navigating stairs. It is aggravated by activities of daily living such as dressing and performing person hygiene. The injured worker reports burning left knee pain which is constant and moderate to severe in intensity. The knee pain is aggravated with squatting, kneeling, navigating stairs, prolonged standing and walking. The pain is revived with medications and activity restrictions. The use of medications allows him relief of pain and improves his sleep. On physical examination the injured worker is able to heel-toe walk with reported pain. He is able to squat to 50% of normal due to pain in the low back. He has tenderness to palpation with spasms over the lumbar spine and a reduced range of motion in all planes. He has tenderness to palpation in the left knee with a limited range of motion. McMurray's sign was positive at the left knee. The diagnoses associated with the request include lumbar disc herniated nucleus pulposus, low back pain, lumbar radiculopathy, left knee sprain/strain, left knee meniscal tear, and left knee pain. The treatment plan includes chiropractic therapy, physiotherapy, Terocin patches for pain, Deprizine, Dicoprofanol, Fanatrex, Synapryn, Tabradol, Gabapentin, Cyclobenzaprine, and Flurbiprofen.

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 500 mg 1 tsp 3 times a day: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 50, 78-80.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain CRITERIA FOR USE OF OPIOIDS Page(s): 60 ,61, 76-78, 88, 89.

Decision rationale: The patient presents on 03/04/15 with burning lower back pain rated 9/10 with associated numbness and tingling in the bilateral lower extremities, burning left knee pain rated 9/10, and associated insomnia secondary to pain. The patient's date of injury is 09/18/13. Patient has no documented surgical history directed at this complaint. The request is for SYNAPRYN (10MG/1ML) ORAL SUSPENSION 500MG 1 TSP 3 TIMES A DAY. The RFA was not provided. Physical examination dated 03/04/15 reveals tenderness to palpation of the lumbar paraspinous muscles, lumbosacral junction, and medial joint line of the left knee. The provider also notes positive straight leg raise test bilaterally and decreased range of motion in the lumbar spine and left knee. The patient is currently prescribed Deprizine, Dicoprofen, Synapryn, Tabradol, Cyclobenzaprine, Gabapentin, and Flurbiprofen. Diagnostic imaging was not provided. Patient's current work status is not provided. MTUS Guidelines pages 88 and 89 states, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS page 78 also requires documentation of the 4As (analgesia, ADLs, adverse side effects, and adverse behavior), as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. MTUS p80, 81 states regarding chronic low back pain: "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited." Long-term use of opiates may be indicated for nociceptive pain as it is "Recommended as the standard of care for treatment of moderate or severe nociceptive pain (defined as pain that is presumed to be maintained by continual injury with the most common example being pain secondary to cancer)." In regard to the request for Synapryn oral suspension, which contains Tramadol, the provider has failed to provide specific pain and specific functional improvements attributed to this medication. It is not clear how long this patient has been prescribed Synapryn, as only one progress note - dated 03/04/15 - was provided. Addressing medication efficacy, progress note 03/04/15 states: "medications do offer him relief of pain and improve his ability to have restful sleep." MTUS guidelines require documentation of analgesia via a validated scale, activity-specific functional improvements, a stated lack of aberrant behavior, and consistent urine drug screening. In this case, there is no validated scale, no activity-specific improvements, no stated lack of aberrant behavior, and no evidence of medication compliance to date. A statement of medical necessity, dated 03/04/15 was also included addressing each of the requested oral suspensions, stating the following: "I have found in the general patient population that I have treated a generation aversion for swallowing pills which is a "red flag" indicator against long term compliance with pharmacological treatment plan that uses standard oral tablet ingestion." However, a review of the associated progress report does not specifically describe whether or not this particular patient has an aversion to taking standard oral medications. The provider does

indicate that this patient has taken standard medications in the past, stating: "This patient presented to me with a history of taking multiple medication for the pain cause by the injury, including chronically taking over-the-counter non-steroidal anti inflammatory medications." It is not clear from these conflicting statements why the patient is unable to swallow standard pills/tablets presently. ACOEM guidelines page 492 considers apparent reasonableness of the treatment including "cost-effectiveness" when considering medical treatments. Given the lack of documentation of the 4A's as required by MTUS for this class of medications, and the lack of an explicit reason that this patient is unable to tolerate standard medications, the medical necessity of this request cannot be substantiated. Therefore, this request IS NOT medically necessary.

Tabradol 1mg per ml oral suspension 250 mg 1 tsp 2-3 times a day: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 63-64.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63-66.

Decision rationale: The patient presents on 03/04/15 with burning lower back pain rated 9/10 with associated numbness and tingling in the bilateral lower extremities, burning left knee pain rated 9/10, and associated insomnia secondary to pain. The patient's date of injury is 09/18/13. Patient has no documented surgical history directed at this complaint. The request is for TABRADOL 1MG PER ML ORAL SUSPENSION 250MG 1 TSP 2-3 TIMES A DAY. The RFA was not provided. Physical examination dated 03/04/15 reveals tenderness to palpation of the lumbar paraspinal muscles, lumbosacral junction, and medial joint line of the left knee. The provider also notes positive straight leg raise test bilaterally and decreased range of motion in the lumbar spine and left knee. The patient is currently prescribed Deprizine, Dicopanol, Synapryn, Tabradol, Cyclobenzaprine, Gabapentin, and Flurbiprofen. Diagnostic imaging was not provided. Patient's current work status is not provided. MTUS pg 63-66 states: "Muscle relaxants (for pain): Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbation in patients with chronic LBP. The most commonly prescribed antispasmodic agents are carisoprodol, cyclobenzaprine, metaxalone, and methocarbamol, but despite their popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. Cyclobenzaprine (Flexeril, Amrix, Fexmid, generic available): Recommended for a short course of therapy." In regard to the request for Tabradol oral suspension, it is unclear why this patient is unable to tolerate standard oral medications. It is not clear how long this patient has been prescribed Tabradol or to what effect, as only one progress report was provided, dated 03/04/15. A statement of medical necessity, dated 03/04/15 was also included addressing each of the requested oral suspensions, stating the following: "I have found in the general patient population that I have treated a generation aversion for swallowing pills which is a "red flag" indicator against long term compliance with pharmacological treatment plan that uses standard oral tablet ingestion." However, a review of the associated progress report does not specifically describe whether or not this particular patient has an aversion to taking standard oral medications. The provider does indicate that this patient has taken standard medications in the past, stating: "This patient presented to me with a history of taking multiple medication for the pain cause by the injury, including chronically taking over-

the-counter non-steroidal anti inflammatory medications." It is not clear from these conflicting statements why the patient is unable to swallow pills/tablets presently. ACOEM guidelines page 492 considers apparent reasonableness of the treatment including "cost-effectiveness" when considering medical treatments. Given the lack of an explicit statement that this patient is unable to tolerate standard oral medications, the medical necessity of this request cannot be substantiated. Therefore, this request IS NOT medically necessary.

Deprizine 15 mg/ml oral suspension 250 ml 2 tsp daily: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68-69.

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

Decision rationale: The patient presents on 03/04/15 with burning lower back pain rated 9/10 with associated numbness and tingling in the bilateral lower extremities, burning left knee pain rated 9/10, and associated insomnia secondary to pain. The patient's date of injury is 09/18/13. Patient has no documented surgical history directed at this complaint. The request is for DEPRIZINE 15MG/ML ORAL SUSPENSION 250ML 2 TSP DAILY. The RFA was not provided. Physical examination dated 03/04/15 reveals tenderness to palpation of the lumbar paraspinal muscles, lumbosacral junction, and medial joint line of the left knee. The provider also notes positive straight leg raise test bilaterally and decreased range of motion in the lumbar spine and left knee. The patient is currently prescribed Deprizine, Dicoprofen, Synapryn, Tabradol, Cyclobenzaprine, Gabapentin, and Flurbiprofen. Diagnostic imaging was not provided. Patient's current work status is not provided. The MTUS, ACOEM, and ODG Guidelines do not specifically discuss Deprizine. However, MTUS page 69 recommends determining risk for GI events before prescribing prophylactic PPI or omeprazole. GI risk factors include: (1) Age is greater than 65, (2) History of peptic ulcer disease and GI bleeding or perforation, (3) Concurrent use of ASA or corticosteroid and/or anticoagulant, (4) High dose/multiple NSAID. Treater has not provided a reason for the request. Progress notes do not indicate that this patient suffers from any GI complaints. Routine prophylactic use of PPI without documentation of gastric issues is not supported by the guidelines without GI-risk assessment. A statement of medical necessity, dated 03/04/15 was included addressing each of the requested oral suspensions, stating the following: "I have found in the general patient population that I have treated a generation aversion for swallowing pills which is a "red flag" indicator against long term compliance with pharmacological treatment plan that uses standard oral tablet ingestion." However, a review of the associated progress report does not specifically describe whether or not this particular patient has an aversion to taking standard oral medications, stating: "This patient presented to me with a history of taking multiple medication for the pain cause by the injury, including chronically taking over-the-counter non-steroidal anti inflammatory medications." ACOEM guidelines page 492 considers apparent reasonableness of the treatment including "cost-effectiveness" when considering medical treatments. Without appropriate GI assessment or complaints of gastric upset secondary to medication usage, and a clear indication that this patient is unable to tolerate standard oral medications, the medical necessity of this medication cannot be substantiated. Therefore, this request IS NOT medically necessary.

Dicopanol 5 mg/ml 150 ml 1 ml po at bedtime: 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 under Insomnia.

Decision rationale: The patient presents on 03/04/15 with burning lower back pain rated 9/10 with associated numbness and tingling in the bilateral lower extremities, burning left knee pain rated 9/10, and associated insomnia secondary to pain. The patient's date of injury is 09/18/13. Patient has no documented surgical history directed at this complaint. The request is for DICOPANOL 5MG/ML PO AT BEDTIME. The RFA was not provided. Physical examination dated 03/04/15 reveals tenderness to palpation of the lumbar paraspinal muscles, lumbosacral junction, and medial joint line of the left knee. The provider also notes positive straight leg raise test bilaterally and decreased range of motion in the lumbar spine and left knee. The patient is currently prescribed Deprizine, Dicopanol, Synapryn, Tabradol, Cyclobenzaprine, Gabapentin, and Flurbiprofen. Diagnostic imaging was not provided. Patient's current work status is not provided. The MTUS, ACOEM, and ODG guidelines do not discuss Dicopanol. Progress note dated 03/04/15 indicates that this medication is being provided for insomnia. ODG guidelines Pain Chapter under Insomnia has the following regarding anti-Histamine for insomnia: (4) Over-the-counter medications: Sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine). Tolerance seems to develop within a few days. Next-day sedation has been noted as well as impaired psychomotor and cognitive function. Side effects include urinary retention, blurred vision, orthostatic hypotension, dizziness, palpitations, increased liver enzymes, drowsiness, dizziness, grogginess and tiredness. ODG states that tolerance develops within a few days and long-term use is not supported. In regard to the request for Dicopanol oral suspension, such medications are not indicated for long term use for insomnia. It is unclear how long this patient has been prescribed Dicopanol or to what effect, as only one progress note was provided, dated 03/04/15. Dicopanol contains diphenhydramine, an anti-histamine. While the provider indicates that this is being prescribed is as a sleep aid, the use of Dicopanol for this function is not supported by ODG guidelines as noted above. A statement of medical necessity, dated 03/04/15 was included addressing each of the requested oral suspensions, stating the following: "I have found in the general patient population that I have treated a generation aversion for swallowing pills which is a "red flag" indicator against long term compliance with pharmacological treatment plan that uses standard oral tablet ingestion." However, a review of the associated progress report does not specifically describe whether or not this particular patient has an aversion to taking standard oral medications, stating: "This patient presented to me with a history of taking multiple medication for the pain cause by the injury, including chronically taking over-the-counter non-steroidal anti inflammatory medications." ACOEM guidelines page 492 considers apparent reasonableness of the treatment including "cost-effectiveness" when considering medical treatments. Owing to a lack of guideline support for this medication's use in treating insomnia, and a lack of a clear statement as to why this patient is unable to tolerate

standard oral medications, the request cannot be substantiated. Therefore, this request IS NOT medically necessary.

Fanatrex (Gabapentin) 25 mg/ml oral suspension 420 ml 1 tsp tid: 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 Gabapentin Page(s): 18, 19.

Decision rationale: The patient presents on 03/04/15 with burning lower back pain rated 9/10 with associated numbness and tingling in the bilateral lower extremities, burning left knee pain rated 9/10, and associated insomnia secondary to pain. The patient's date of injury is 09/18/13. Patient has no documented surgical history directed at this complaint. The request is for FANATREX (GABAPENTIN) 25 MG/ML ORAL SUSPENSION 420ML 1 TSP TID. The RFA was not provided. Physical examination dated 03/04/15 reveals tenderness to palpation of the lumbar paraspinal muscles, lumbosacral junction, and medial joint line of the left knee. The provider also notes positive straight leg raise test bilaterally and decreased range of motion in the lumbar spine and left knee. The patient is currently prescribed Deprizine, Dicopanol, Synapryn, Tabradol, Cyclobenzaprine, Gabapentin, and Flurbiprofen. Diagnostic imaging was not provided. Patient's current work status is not provided. Fanatrex contains Gabapentin and other proprietary ingredients. The MTUS Guidelines page 18 and 19 has the following regarding Gabapentin, "Gabapentin has been shown to be effective for treatment of diabetic painful neuropathy and post-therapeutic neuralgia and has been considered a first-line treatment for neuropathic pain." In regard to the Fanatrex oral suspension, it is not clear why this patient cannot tolerate standard oral medications. This patient does present with significant lumbar disc pathology and neuropathic pain, for which Gabapentin would be indicated. Per progress note 03/04/15, this patient does note temporary pain relief attributed to medications, though Fanatrex is not specifically mentioned. A statement of medical necessity, dated 03/04/15 was included addressing each of the requested oral suspensions, stating the following: "I have found in the general patient population that I have treated a generation aversion for swallowing pills which is a "red flag" indicator against long term compliance with pharmacological treatment plan that uses standard oral tablet ingestion." However, a review of the associated progress report does not specifically describe whether or not this particular patient has an aversion to taking standard oral medications, stating: "This patient presented to me with a history of taking multiple medication for the pain cause by the injury, including chronically taking over-the-counter non-steroidal anti-inflammatory medications." ACOEM guidelines page 492 considers apparent reasonableness of the treatment including "cost-effectiveness" when considering medical treatments, without a clearer rationale as to why this patient is unable to tolerate standard oral medications, the requested oral suspension cannot be substantiated. Therefore, this request IS NOT medically necessary.

Chiropractic treatment 3 times a week for 6 weeks: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Manual Therapy and Manipulation Page(s): 40.

Decision rationale: The patient presents on 03/04/15 with burning lower back pain rated 9/10 with associated numbness and tingling in the bilateral lower extremities, burning left knee pain rated 9/10, and associated insomnia secondary to pain. The patient's date of injury is 09/18/13. Patient has no documented surgical history directed at this complaint. The request is for **CHIROPRACTIC TREATMENT 3 TIMES A WEEK FOR 6 WEEKS**. The RFA was not provided. Physical examination dated 03/04/15 reveals tenderness to palpation of the lumbar paraspinal muscles, lumbosacral junction, and medial joint line of the left knee. The provider also notes positive straight leg raise test bilaterally and decreased range of motion in the lumbar spine and left knee. The patient is currently prescribed Deprizine, Dicopanol, Synapryn, Tabradol, Cyclobenzaprine, Gabapentin, and Flurbiprofen. Diagnostic imaging was not provided. Patient's current work status is not provided. MTUS Chronic Pain Medical Treatment Guidelines, page 40, regarding Manual Therapy and Manipulation state: "Recommended for chronic pain if caused by musculoskeletal conditions and manipulation is specifically recommended as an option for acute 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 function 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. Treatment Parameters from state guidelines a. Time to produce objective functional gains: 3-5 treatments b. Frequency: 1-5 supervised treatments per week the first 2 weeks, decreasing to 1-3 times per week for the next 6 weeks, then 1-2 times per week for the next 4 weeks, if necessary. c. Optimum duration: Treatment beyond 3-6 visits should be documented with objective improvement in function. Palliative care should be reevaluated and documented at each treatment session." In regard to the request for 18 sessions of chiropractic care for this patient's lower back complaint, the provider has exceeded guideline recommendations. There is no indication in the records provided that this patient has had any chiropractic treatment to date. MTUS guidelines support manual manipulation as an appropriate treatment modality, though require documentation of objective functional improvements to continue treatment beyond 3-5 sessions. In this case, the provider is requesting 18 sessions without first establishing efficacy. Were the request for 3-5 treatments, the recommendation would be for approval, though the current request as written exceeds guideline recommendations and cannot be substantiated. Therefore, the request IS NOT medically necessary.