

Case Number:	CM14-0214863		
Date Assigned:	01/07/2015	Date of Injury:	11/19/2010
Decision Date:	02/28/2015	UR Denial Date:	11/21/2014
Priority:	Standard	Application Received:	12/22/2014

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

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 patient is a 33 year old male with an injury date of 11/19/10. Based on the 10/23/14 progress report provided by treating physician, the patient complains of lower back and sacral pain rated 6/10 which radiates into the bilateral lower extremities (right worse than left) with associated numbness and tingling in the right foot. Additionally, physician notes patient comments that he is currently going through medication withdrawals. Patient is status post lumbar ESI dated 11/11/13. Physical examination dated 10/23/14 revealed tenderness to palpation to bilateral sacroiliac joints, positive Faber's sign and straight leg test at 40 degrees, palpable paralumbar muscle spasm, and decreased sensitivity to right lower extremity in the L4/L5 dermatomal distribution. The patient is currently prescribed Clonazepam, Roxicodone. Patient is currently working, though with physical restrictions. Diagnostic imaging included lumbar MRI dated 07/28/14, significant findings include: "L3-S1 disc space loss and dehydration, L3/L4 4mm focal central disc extrusion indenting the thecal sac and producing central canal stenosis, L4/L5 2.7mm focal disc protrusion." Diagnosis 10/23/14- Lumbar disc displacement- Low back pain- Lumbar radiculopathy- Sacrolitis- Adjustment disorder with anxiety The utilization review determination being challenged is dated 11/21/14. The rationale follows: 1) Tabradol: "evidence based guidelines do not consistently support muscle relaxants in the management of chronic pain, but do support use in the management of acute muscle spasms, there is no documentation of acute spasms and the intention to treat over a short course." 2) Synapryn: "there is no documentation of a statement identifying why a compounded medication are needed for this patient." 3) Deprizine: "there is no documentation of GI disorders or patient's utilizing chronic

NSAID therapy."4) Dicopanal: "medical practice standard of care makes it reasonable to require documentation of a statement identifying why a compounded medication are needed for this patient."5) Fanatrex: "there is documentation of neuropathic pain however there is no documentation of why the tablet form was not attempted."Treatment reports were provided from 06/06/14 to 10/23/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tabradol 1mg/ml oral suspension 250ml: Upheld

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

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

Decision rationale: The patient presents with lower back and sacral pain rated 6/10 which radiates into the bilateral lower extremities (right worse than left) with associated numbness and tingling in the right foot. Additionally, physician notes patient comments that he is currently going through medication withdrawals. Patient is status post lumbar ESI dated 11/11/13. The request is for TABRADOL 1MG/ML ORAL SUSPENSION 250 ML. Physical examination dated 10/23/14 revealed tenderness to palpation to bilateral sacroiliac joints, positive Faber's sign and straight leg test at 40 degrees, palpable paralumbar muscle spasm, and decreased sensitivity to right lower extremity in the L4/L5 dermatomal distribution. The patient is currently prescribed Clonazepam, Roxycodone. Patient is currently working, though with physical restrictions. Diagnostic imaging included lumbar MRI dated 07/28/14.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." In regards to the request for Tabradol oral suspension, which contains Cyclobenzaprine, the treating physician has not provided a reason for the request. While the patient does present with lumbar spasms secondary to his disc disorder, the treating physician does not discuss any reason for prescribing this medication for reasons other than for subjective pain. There are no discussions of flare ups, or acute exacerbation of the patient's muscle spasms. Furthermore, the treating physician provides no discussions as to why oral suspensions are being requested. ACOEM guidelines page 492 considers apparent reasonableness of the treatment including "cost-effectiveness" when considering medical treatments. Therefore, this request IS NOT medically necessary.

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

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://dailymed.nlm.nih.gov/dailymed/druginfo.cfm?id=20039>

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for Use of Opioids, Medication for chronic pain Page(s): 88-89, 76-78; 60-61.

Decision rationale: The patient presents with lower back and sacral pain rated 6/10 which radiates into the bilateral lower extremities (right worse than left) with associated numbness and tingling in the right foot. Additionally, physician notes patient comments that he is currently going through medication withdrawals. Patient is status post lumbar ESI dated 11/11/13. The request is for SYNAPRYN 10MG/ML ORAL SUSPENSION 500ML. Physical examination dated 10/23/14 revealed tenderness to palpation to bilateral sacroiliac joints, positive Faber's sign and straight leg test at 40 degrees, palpable paralumbar muscle spasm, and decreased sensitivity to right lower extremity in the L4/L5 dermatomal distribution. The patient is currently prescribed Clonazepam, Roxicodone. Patient is currently working, though with physical restrictions. Diagnostic imaging included lumbar MRI dated 07/28/14. MTUS Guidelines pages 88 and 89 state, "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 4 A's (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. In regards to the request for Synapryn oral suspension, which contains Tramadol, the treating physician has failed to provide specific pain and specific functional improvements attributed to this medication. Though the progress note dated 10/23/14 indicates that this patient has been able to return to work, which can be considered evidence of functional improvement, it appears that this medication is able to produce some benefits. That being said, no rationale for the utilization of an oral suspension is provided, it is not clear why the patient is unable to swallow pills. ACOEM guidelines page 492 considers apparent reasonableness of the treatment including "cost-effectiveness" when considering medical treatments. Therefore, this request 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 National Library of Medicine, <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000094/> ; <http://www.drugs.com/pro/deprizine.html>

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 16 Eye Chapter Page(s): 492, Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk Page(s): 68-69.

Decision rationale: The patient presents with lower back and sacral pain rated 6/10 which radiates into the bilateral lower extremities (right worse than left) with associated numbness and tingling in the right foot. Additionally, physician notes patient comments that he is currently going through medication withdrawals. Patient is status post lumbar ESI dated 11/11/13. The request is for DEPRIZINE 15MG/ML ORAL SUSPENSION 250ML. Physical examination dated 10/23/14 revealed tenderness to palpation to bilateral sacroiliac joints, positive Faber's sign

and straight leg test at 40 degrees, palpable paralumbar muscle spasm, and decreased sensitivity to right lower extremity in the L4/L5 dermatomal distribution. The patient is currently prescribed Clonazepam, Roxicodone. Patient is currently working, though with physical restrictions. Diagnostic imaging included lumbar MRI dated 07/28/14. 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. Treating physician has not provided a reason for the request. Progress notes do not indicate that this patient suffers from any significant GI complaints, nor is he currently taking high dose or multiple NSAIDs. Routine prophylactic use of PPI without documentation of gastric issues is not supported by the guidelines without GI-risk assessment. Furthermore, the treating physician provides no discussions as to why oral suspensions are being requested. ACOEM guidelines page 492 considers apparent reasonableness of the treatment including "cost-effectiveness" when considering medical treatments. Therefore, this request IS NOT medically necessary.

Dicopanol 5mg/ml oral suspension 150ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 16 Eye Chapter Page(s): 492. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Insomnia treatment.

Decision rationale: The patient presents with lower back and sacral pain rated 6/10 which radiates into the bilateral lower extremities (right worse than left) with associated numbness and tingling in the right foot. Additionally, physician notes patient comments that he is currently going through medication withdrawals. Patient is status post lumbar ESI dated 11/11/13. The request is for DICOPANAL 5MG/ML ORAL SUSPENSION 150ML. Physical examination dated 10/23/14 revealed tenderness to palpation to bilateral sacroiliac joints, positive Faber's sign and straight leg test at 40 degrees, palpable paralumbar muscle spasm, and decreased sensitivity to right lower extremity in the L4/L5 dermatomal distribution. The patient is currently prescribed Clonazepam, Roxicodone. Patient is currently working, though with physical restrictions. Diagnostic imaging included lumbar MRI dated 07/28/14. The MTUS, ACOEM, and ODG guidelines do not discuss Dicopanol. Though the treating physician has not discussed a reason for this request, presumably it is for the treatment of patient's insomnia secondary to anxiety disorder and chronic pain. ODG guidelines Pain Chapter under Insomnia have 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. Treating physician has not provided a reason for the request. Dicopanol

contains diphenhydramine, an anti-histamine. While the patient's psychiatric complaints seem to indicate that the reason this medication is being prescribed is as a sleep aid, the use of Dicopanol for this function is not supported by ODG guidelines as noted above. Furthermore, the treating physician provides no discussions as to why oral suspensions are being requested. ACOEM guidelines page 492 considers apparent reasonableness of the treatment including "cost-effectiveness" when considering medical treatments. Therefore, this request IS NOT medically necessary.

Fanatrex 25mg/ml oral suspension 420ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation National Library of Medicine, (<http://www.ncbi.nih.gov/pubmedhealth/PMH0000704/>)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Medication for Chronic Pain Page(s): 18-19; 60-61.

Decision rationale: The patient presents with lower back and sacral pain rated 6/10 which radiates into the bilateral lower extremities (right worse than left) with associated numbness and tingling in the right foot. Additionally, physician notes patient comments that he is currently going through medication withdrawals. Patient is status post lumbar ESI dated 11/11/13. The request is for FANATREX 25MG/ML ORAL SUSPENSION 420ML. Physical examination dated 10/23/14 revealed tenderness to palpation to bilateral sacroiliac joints, positive Faber's sign and straight leg test at 40 degrees, palpable paralumbar muscle spasm, and decreased sensitivity to right lower extremity in the L4/L5 dermatomal distribution. The patient is currently prescribed Clonazepam, Roxicodone. Patient is currently working, though with physical restrictions. Diagnostic imaging included lumbar MRI dated 07/28/14. 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." While this patient does present with significant lumbar disc pathology and neuropathic pain, for which Gabapentin would be indicated. But there is no documentation this medication has been helpful with the patient's neuropathic pain. MTUS page 60 require recording of pain and function with medications used for chronic pain. There is also no rationale provided for the utilization of an oral suspension. It is not clear why the patient is unable to swallow pills. ACOEM guidelines page 492 considers apparent reasonableness of the treatment including "cost-effectiveness" when considering medical treatments. Therefore, this request IS NOT medically necessary.