MAXIMUS Federal Services

Case Number:	CM15-0209518		
Date Assigned:	10/29/2015	Date of Injury:	05/22/2014
Decision Date:	12/14/2015	UR Denial Date:	09/23/2015
Priority:	Standard	Application Received:	10/23/2015

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 44 year old male, who sustained an industrial injury on 05-22-2014. He has reported injury to the low back. The diagnoses have included lumbar spine sprain-strain; lumbar herniated nucleus pulposus (as per MRI, 05-21-2015); lumbar degenerative disc disease; Schmorl's node at L5; and lumbar radiculopathy. Treatment to date has included medication, diagnostics, activity modification, chiropractic therapy, shockwave therapy, and physical therapy. Medications have included Deprizine, Synapryn, Tabradol, Dicopanol, Fanatrex, Ketoprofen cream, Cyclobenzaprine cream, and topical compounded creams. A progress note from the treating physician, dated 08-31-2015, documented a follow-up visit with the injured worker. The injured worker reported burning, radicular low back pain and muscle spasms; he rates the pain as 7 out of 10 in intensity on a pain analog scale; the pain is described as constant and moderate to severe; the pain is associated with numbness and tingling of the bilateral lower extremities, greater on the right side; the pain is aggravated by prolonged positioning including sitting, standing, walking, bending, and stooping; his pain is also aggravated by activities of daily living such as getting dressed and performing personal hygiene; the symptoms persist, but the medications do offer him temporary relief of pain and improve his ability to have restful sleep; he denies any problems with the medications; and the pain is also alleviated by activity restrictions. Objective findings included he appears to be in no acute distress; there is tenderness to palpation at the lumbar paraspinal muscles; there is a trigger point noted; lumbar spine ranges of motion are decreased; there is slightly decreased sensation to pin-prick and light touch at the L4, L5, and S1 dermatomes bilaterally; and motor strength is 4 out of 5 in all represented muscle

groups in the bilateral lower extremities. The treatment plan has included the request for Deprizine 15mg/ml 250ml; Dicopanol 5mg/ml 150ml; and Fanatrex 25mg/ml 420ml. The original utilization review, dated 09-23-2015, non-certified the request for Deprizine 15mg/ml 250ml; Dicopanol 5mg/ml 150ml; and Fanatrex 25mg/ml 420ml.

IMR ISSUES, DECISIONS AND RATIONALES

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

Deprizine 15mg/ml 250ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain - Compound drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: The 44 year old patient complains of radicular low back pain and muscle spasms, rated at 7/10, along with numbness and tingling of bilateral lower extremities, as per progress report dated 08/31/15. The request is for DEPRIZINE 15mg/ml 250ml. The RFA for this case is dated 07/30/15, and the patient's date of injury is 05/22/14. Diagnoses, as per progress report dated 08/31/15, lumbar spine sprain/strain, lumbar spine HNP, lumbar degenerative disc disease, Schmori's nodule at L5, and lumbar radiculopathy. Medications included Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Cyclobenzaprine, Ketoprofen, and compounded creams. The patient is off work, as per the same report. Deprizine is ranitidine (zantac, H2-receptor antagonist) mixed with other proprietary ingredients in an oral suspension. The MTUS, ACOEM, and ODG Guidelines do not specifically discuss Deprizine. However, MTUS guidelines, NSAIDs, GI symptoms & cardiovascular risk section, pages 68-69 states that "Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA)." "Treatment of dyspepsia secondary to NSAID therapy: Stop the NSAID, switch to a different NSAID, or consider H2-receptor antagonists or a PPI." In this case, Deprizine is first noted in progress report dated 02/03/15. It is not clear when the medication was initiated. As per progress report dated 08/31/15, the patient has been taking multiple medications to manage chronic pain including over-the-counter NSAIDs. He is, therefore, at an increased risk of gastrointestinal perforation / hemorrhage. The treater also explains that "I have found empirically that patients with chronic conditions have responded well to oral solutions," possibly due to the flavor or aversion to swallowing multiple pills. Prophylactic use of PPI is indicated by MTUS, and the patient is on NSAID therapy. However, there is no evidence of gastric problems, and there is no mention of GI issues the patient might be suffering from. Furthermore, the patient is under 65 years of age and there is no indication of concurrent use of ASA, corticosteroids, and/or an anticoagulant. Additionally, 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. Hence, the request IS NOT medically necessary.

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 Official Disability Guidelines (ODG), Pain - Compound drugs.

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 44 year old patient complains of radicular low back pain and muscle spasms, rated at 7/10, along with numbness and tingling of bilateral lower extremities, as per progress report dated 08/31/15. The request is for DICOPANOL 5mg/ml 150ml. The RFA for this case is dated 07/30/15, and the patient's date of injury is 05/22/14. Diagnoses, as per progress report dated 08/31/15, lumbar spine sprain/strain, lumbar spine HNP, lumbar degenerative disc disease, Schmori's nodule at L5, and lumbar radiculopathy. Medications included Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Cyclobenzaprine, Ketoprofen, and compounded creams. The patient is off work, as per the same report.ODG guidelines, Pain Chapter under Insomnia has the following regarding anti-Histamine: (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 this case, Dicopanol is first noted in progress report dated 02/03/15. It is not clear when the medication was initiated. In progress report dated 08/31/15, the treater states that the patient "presented to me with a history of an irregular sleeping pattern, complaining of rarely getting a continuous night of sleep, and often of difficulty in falling asleep." The treater further mentions that Dicopanol is reasonable and necessary for the management of the patient's insomnia. As per the same report, medications offer temporary relief of pain and improve his ability to have restful sleep. There are no side effects. The treater also explains that "I have found empirically that patients with chronic conditions have responded well to oral solutions," possibly due to the flavor or aversion to swallowing multiple pills. However, 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. Additionally, Dicopanol contains diphenhydramine, an anti-histamine, and ODG states that tolerance develops within a few days. Hence, long-term use is not supported. The patient has been using this medication for several months. Therefore, the request IS NOT medically necessary.

Fanatrex 25mg/ml 420ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain - Compound drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs).

Decision rationale: The 44 year old patient complains of radicular low back pain and muscle spasms, rated at 7/10, along with numbness and tingling of bilateral lower extremities, as per progress report dated 08/31/15. The request is for FANATREX 25mg/ml 420m. The RFA for this case is dated 07/30/15, and the patient's date of injury is 05/22/14. Diagnoses, as per progress report dated 08/31/15, lumbar spine sprain/strain, lumbar spine HNP, lumbar degenerative disc disease, Schmori's nodule at L5, and lumbar radiculopathy. Medications included Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Cyclobenzaprine, Ketoprofen, and compounded creams. The patient is off work, as per the same report. MTUS Chronic Pain Medical Treatment Guidelines 2009 has the following regarding Gabapentin on pg 18,19, Specific Anti-epilepsy Drugs section and Chronic Pain Medical Treatment Guidelines 2009: "Gabapentin (Neurontin, Gabarone, generic available) has been shown to be effective for treatment of diabetic painful neuropathy and post-therapeutic neuralgia and has been considered as a first-line treatment for neuropathic pain."In this case, Fanatrex is first noted in progress report dated 02/03/15. It is not clear when the medication was initiated. In progress report dated 08/31/15, the treater states that the patient "presented to me with a clear history of neuropathic pain. The patient found it difficult to describe their pain precisely." The reports indicate that medications "offer temporary relief of pain and improve his ability to have restful sleep." There are no side effects. The treater also explains that "I have found empirically that patients with chronic conditions have responded well to oral solutions," possibly due to the flavor or aversion to swallowing multiple pills. However, 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. Additionally, the treater does not document the impact of Fanatrex on the patient's function, as required by MTUS page 60 for all pain medications. Hence, the request IS NOT medically necessary.