

Case Number:	CM15-0106215		
Date Assigned:	06/11/2015	Date of Injury:	12/08/2011
Decision Date:	09/22/2015	UR Denial Date:	05/26/2015
Priority:	Standard	Application Received:	06/03/2015

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 67 year old male who sustained an industrial injury on 12/08/2011. The injured worker was diagnosed with right knee internal derangement, chondromalacia and status post right knee arthroscopy (no date documented). Treatment to date includes activity restriction, conservative measures, surgery, assistive walking device and medications. According to the primary treating physician's progress report on February 18, 2015, the injured worker continues to experience residual pain post arthroscopy with swelling of the right knee. The injured worker rates his pain level at 8/10. The injured worker ambulates with a cane. Examination demonstrated tenderness to palpation over the medial joint line, pes anserinus bursa, patellofemoral joint and surgical portals. There was 2+ effusion noted. The injured worker was able to heel-toe walk with pain at the right knee. No instability of the ligaments was noted. Range of motion was decreased with slight decrease in sensory at the L4, L5 and S1 dermatomes in the right lower extremity. Muscle strength was 4/5 in the lower extremities with symmetrical 2+ deep tendon reflexes and pulses bilaterally. Current medications are listed as Synapryn, Tabradol, Deprizine, Dicopanol and Fanatrex. Treatment plan consists of physical therapy for the right knee, orthopedic surgical consultation, shockwave therapy, Terocin patches and the current request for Synapryn (10mg/ml oral suspension), Tabradol (1mg/ml oral suspension), Deprizine (15mg/ml oral suspension), Dicopanol (diphenhydramine) (5mg/ml oral suspension) and Fanatrex (Gabapentin) (25mg/ml oral suspension).

IMR ISSUES, DECISIONS AND RATIONALES

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

Synapryn (10mg/ml oral suspension) #500ml: 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 Medications for chronic pain CRITERIA FOR USE OF OPIOIDS Page(s): 60, 61, 76-78, 88, 89.

Decision rationale: The patient was injured on 12/08/11 and presents with right knee pain. The request is for SYNAPRYN (10 MG/ML ORAL SUSPENSION) #500 ML. There is no RFA provided and the patient's current work status is not provided. The patient has been taking this medication as early as 01/07/15. 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. The patient is diagnosed with right knee internal derangement, chondromalacia and status post right knee arthroscopy (no date documented). On 01/07/15, he rated his pain as a 7-8/10. On 02/18/15, the patient rated his pain as an 8/10. "The medications do offer him temporary relief of pain and improve his ability to have restful sleep." In this case, none of the 4As are addressed as required by MTUS Guidelines. Although the treater provides general pain scales, there are no before and after medication pain scales. There are no examples of ADLs which demonstrate medication efficacy, nor are there any discussions provided on adverse behavior/side effects. No validated instruments are used either. There are no pain management issues discussed such as CURES report, pain contract, et cetera. No outcome measures are provided as required by MTUS Guidelines. The treater did not provide a urine drug screen to see if the patient is compliant with his prescribed medications. The treating physician does not provide adequate documentation that is required by MTUS Guidelines for continued opiate use. Therefore, the requested Synapryn IS NOT medically necessary.

Tabradol (1mg/ml oral suspension) #250ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril).

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

Decision rationale: The patient was injured on 12/08/11 and presents with right knee pain. The request is for TABRADOL (1 MG/ML ORAL SUSPENSION) #250 ML. There is no RFA provided and the patient's current work status is not provided. The patient has been taking this medication as early as 01/07/15. Tabradol contains cyclobenzaprine, methylsufonylmethane and other proprietary ingredients. The MTUS Guidelines page 63-66 states, "muscle relaxants, for

pain: Recommended non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. The most commonly prescribed antispasmodic agents are Carisoprodol, cyclobenzaprine, metaxalone, and methocarbamol, but despite the popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions." The patient is diagnosed with right knee internal derangement, chondromalacia and status post right knee arthroscopy (no date documented). The patient has been prescribed this medication as early as 01/07/15. MTUS Guidelines supports the use of cyclobenzaprine for short course of therapy, not longer than 2 to 3 weeks. Given this patient has been using this medication chronically, with no documentation of specific efficacy and functional benefit from Tabradol, the request IS NOT medically necessary.

Deprizine (15mg/ml oral suspension) #250ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Chronic Pain, NSAIDs.

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

Decision rationale: The patient was injured on 12/08/11 and presents with right knee pain. The request is for DEPRIZINE (15 MG/ML ORAL SUSPENSION) #250 ML. There is no RFA provided and the patient's current work status is not provided. The patient has been taking this medication as early as 01/07/15. 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 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. The patient is diagnosed with right knee internal derangement, chondromalacia and status post right knee arthroscopy (no date documented). As of 04/01/15, the patient is taking Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, and Cyclobenzaprine. In this case, the patient is not over 65, does not have a history of peptic ulcer disease and GI bleeding or perforation, does not have concurrent use of ASA or corticosteroid and/or anticoagulant, and does not have high-dose/multiple NSAID. Furthermore, there is no documentation of any NSAIDs the patient is taking. In addition, Deprizine contains ranitidine and "other proprietary ingredients" that is not disclosed. Without knowing what is contained in these medications, it cannot be considered for authorization. The treating physician provides no discussion as to why oral suspensions are being requested. The requested Deprizine IS NOT medically necessary.

Dicopanol (diphenhydromine) (5mg/ml oral suspension) #150ml: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness & Stress Chapter, under Insomnia.

Decision rationale: The patient was injured on 12/08/11 and presents with right knee pain. The request is for DICOPANOL (DIPHENHYDROMINE) (5 MG/ML ORAL SUSPENSION) #150 ML. There is no RFA provided and the patient's current work status is not provided. The patient has been taking this medication as early as 01/07/15. ODG-TWC, Mental Illness & Stress Chapter, under Insomnia states: "(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." The patient is diagnosed with right knee internal derangement, chondromalacia and status post right knee arthroscopy (no date documented). Although the patient is not diagnosed with a sleeping disorder, "the medications do offer him temporary relief of pain and improve his ability to have restful sleep," according to the 02/18/15 report. Dicopanol contains diphenhydramine, an anti-histamine. ODG states that tolerance develops within a few days and long-term use is not supported. In this case there is no long term support for Dicopanol usage and the treating physician has not stated that this medication for short term usage. Furthermore, Dicopanol contains diphenhydramine and "other proprietary ingredients" that is not disclosed. Without knowing what is contained in these medications, it cannot be considered for authorization. In addition, the treating physician provides no discussion as to why oral suspensions are being requested. Therefore, this requested Dicopanol IS NOT medically necessary.

Fanatrex (Gabapentin) (25mg/ml oral suspension) #420ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs); Neurontin (gabapentin).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 18, 19.

Decision rationale: The patient was injured on 12/08/11 and presents with right knee pain. The request is for FANATREX (GABAPENTIN) (25 MG/ML ORAL SUSPENSION) #420 ML. There is no RFA provided and the patient's current work status is not provided. The patient has been taking this medication as early as 01/07/15. MTUS has the following regarding Gabapentin on page 18-19: "Gabapentin (Neurontin, Gabarone, generic available) has 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 patient is diagnosed with right knee internal derangement, chondromalacia and status post right knee arthroscopy (no date documented). In this case, the patient has been taking this medication since 01/07/15. The treater does not discuss efficacy specific to Fanatrex. There is no discussion as to how this medication has been helpful with pain and function. MTUS page 60 require recording of pain and function when medications are used for chronic pain. Furthermore, Fanatrex contains gabapentin and

"other proprietary ingredients" that is not disclosed. Without knowing what is contained in these medications, it cannot be considered for authorization. The treating physician provides no discussion as to why oral suspensions are being requested. The requested Fanatrex IS NOT medically necessary.