

Case Number:	CM14-0216310		
Date Assigned:	01/06/2015	Date of Injury:	06/22/2012
Decision Date:	03/09/2015	UR Denial Date:	12/11/2014
Priority:	Standard	Application Received:	12/24/2014

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: Pennsylvania

Certification(s)/Specialty: Internal Medicine, Hospice & Palliative 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 69-year-old woman with a date of injury of 06/22/2012. A treating physician note dated 12/01/2014 identified the mechanism of injury as repetitive movements resulting in pain throughout the worker's body and joints. Treating physician notes dated 10/31/2014 and 12/01/2014 indicated the worker was experiencing neck pain that went into the mid-back, numbness and tingling in both hands, headaches, blurred vision, arm weakness, lower back pain that went into the right groin, and feet weakness. The worker was also experiencing pain in both elbows, wrists, ahnds, knee, heels, and the right leg. Documented examinations consistently described tenderness in the upper and lower back, positive cervical compression testing, tenderness in both wrists and knees, positive Apley's and McMurray's signs, and tenderness in the right ankle and both feet. The submitted and reviewed documentation concluded the worker was suffering from cervical sprain; strain/sprain of both elbows, wrists, and knees; plantar fasciitis involving both feet, and right metatarsalgia. Treatment recommendations included medications, periodic urinary drug screen testing, continued physical therapy, shockwave therapy, consultation with pain management and orthopedic specialists, and follow up care. A Utilization Review decision was rendered on 12/11/2014 recommending non-certification for shockwave therapy to the neck/upper and lower back and to both knees, feet, elbows, and wrists; 500mL of Synapryn (tramadol and other ingredients) 10mg/mL; 250mL of Tabradol (cyclobenzaprine, methylsulfonylmethane and other ingredients) 1mg/mL; 250mL of Deprizine (ranitidine and other ingredients) 15mg/mL; 150mL of Dicopanол (diphenhydramine

and other ingredients) 5mg/mL; and 420mL of Fanatrex (gabapentin and other ingredients) 25mg/mL.

IMR ISSUES, DECISIONS AND RATIONALES

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

Shockwave Therapy for The Cervical Spine, Bilateral Elbow, Bilateral Wrist, Lumbar Spine, Bilateral Knees and Bilateral Foot: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints, Chapter 10 Elbow Disorders (Revised 2007), Chapter 14 Ankle and Foot Complaints Page(s): 203, 371, 29, 40.

Decision rationale: The ACOEM Guidelines support the use of shock wave therapy for some cases of calcifying shoulder tendinitis and plantar fasciitis, although the literature is limited. There is no good literature to support the use of shock wave therapy for back, elbow, knee, or wrist issues. The submitted and reviewed documentation did not include a discussion of special circumstances that sufficiently supported this request. In the absence of such evidence, the current request for shockwave therapy to the neck/upper and lower back and to both knees, feet, elbows, wrists is not medically necessary.

Synapryn 10 MG/1 ML Oral Suspension 500 ML #1: 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)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Weaning of Medications Page(s): 74-95, 124.

Decision rationale: Synapryn (tramadol and other ingredients) is a medication in the opioid class. The MTUS Guidelines stress the lowest possible dose of opioid medications should be prescribed to improve pain and function, and monitoring of outcomes over time should affect treatment decisions. Documentation of pain assessments should include the current pain intensity, the lowest intensity of pain since the last assessment, the average pain intensity, pain intensity after taking the opioid medication, the amount of time it takes to achieve pain relief after taking the opioid medication, the length of time the pain relief lasts, use and of drug screening with issues of abuse or addiction. Acceptable results include improved function, decreased pain, and/or improved quality of life. The MTUS Guidelines recommend opioids be continued when the worker has returned to work and if the worker has improved function and pain control. When these criteria are not met, an individualized taper is recommended. The submitted and reviewed records concluded the worker was suffering from cervical sprain; strain/sprain of both elbows, wrists, and knees; plantar fasciitis involving both feet, and right metatarsalgia. The documented pain assessments were minimal and included few of the

elements encouraged by the Guidelines. There was no indication the worker had improved pain intensity or function with this specific medication, a detailed individualized risk assessment was not provided, and there was no documented exploration of potential negative effects. Further, there was no indication what additional ingredients were contained in this medication or discussion sufficiently supporting the worker's need for these additional ingredients. In the absence of such evidence, the current request for 500mL of Synapryn (tramadol and other ingredients) 10mg/mL is not medically necessary. While the Guidelines support the use of an individualized taper to avoid withdrawal effects, the risks of continued use significantly outweigh the benefits in this setting based on the submitted documentation, and a wean should be able to be completed with the medication available to the worker.

Tabradol 1 MG/ML Oral Suspension 250 ML #1: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants; Weaning of Medications Page(s): 63-66, 124.

Decision rationale: Tabradol (cyclobenzaprine, methylsulfonylmethane and other ingredients) is a medication in the antispasmodic muscle relaxant class with a food supplement and other ingredients. The MTUS Guidelines support the use of muscle relaxants with caution as a second-line option for short-term use in the treatment of a recent flare-up of long-standing lower back pain. Some literature suggests these medications may be effective in decreasing pain and muscle tension and in increasing mobility, although efficacy decreases over time. In most situations, however, using these medications does not add additional benefit over the use of non-steroidal anti-inflammatory drugs (NSAIDs), nor do they add additional benefit in combination with NSAIDs. Negative side effects, such as sedation, can interfere with the worker's function, and prolonged use can lead to dependence. The submitted and reviewed records concluded the worker was suffering from cervical sprain; strain/sprain of both elbows, wrists, and knees; plantar fasciitis involving both feet, and right metatarsalgia. There was no discussion detailing extenuating circumstances that would support the recommended long-term use. There also was no suggestion that the worker was having a new symptom flare. Further, there was no indication what additional ingredients were contained in this medication or discussion sufficiently supporting the worker's need for these additional ingredients. In the absence of such evidence, the current request for 250mL of Tabradol (cyclobenzaprine, methylsulfonylmethane and other ingredients) 1mg/mL is not medically necessary. Because the potentially serious risks outweigh the benefits in this situation based on the submitted documentation, an individualized taper should be able to be completed with the medication the worker has available.

Deprizine 15 MG/ML Oral Suspension 250 ML #1: 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)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, Gastrointestinal Symptoms and Cardiovascular Risk Page(s): 68-69. Decision based on Non-MTUS Citation Ranitidine: Drug information. Topic 9853, version 145.0. UpToDate, accessed 03/05/2015

Decision rationale: Deprizine (ranitidine and other ingredients) is a medication in the H2-blocker class. The FDA approves the use of this medication to treat heartburn symptoms. The MTUS Guidelines support the use of a proton pump inhibitor when there is an intermediate or high risk of gastrointestinal events and a non-steroidal anti-inflammatory drug (NSAIDs) is prescribed for pain control. The FDA also approves the use of both of these classes of medication for short-term treatment of active ulcers in the stomach or part of the small intestine, heartburn, symptoms associated with gastroesophageal reflux disease (GERD), conditions causing very high amounts of acid in the stomach, and as part of treatment for a specific kind of infection that can cause ulcers. The submitted and reviewed records concluded the worker was suffering from cervical sprain; strain/sprain of both elbows, wrists, and knees; plantar fasciitis involving both feet, and right metatarsalgia. There was no suggestion the worker had any symptoms or signs of any of the conditions this medication is used to treat. There also was no discussion describing special circumstances that sufficiently support the use of this medication in this setting. Further, there was no indication what additional ingredients were contained in this medication or discussion sufficiently supporting the worker's need for these additional ingredients. In the absence of such evidence, the current request for 250mL of Deprizine (ranitidine and other ingredients) 15mg/mL is not medically necessary.

Dicopanol 5 MG/ML Oral Suspension 150 ML #1: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Diphenhydramine: Drug information. Topic 9109, version 139.0. UpToDate, accessed 03/05/2015. Schutte-Rodin S, et al. Clinical guideline for the evaluation and management of chronic insomnia in adults. J Clin Sleep Med. Oct 15 2008; 4(5): 487-504. (American Academy of Sleep Medicine (AASM) Guideline). Chawla J, et al. Reference Topic Insomnia, Medscape. <http://emedicine.medscape.com/article/1187829-overview#aw2aab6b2b2>. Accessed 03/03/2015.

Decision rationale: Dicopanol (diphenhydramine and other ingredients) is a medication in the first-generation antihistamine drug class. The MTUS Guidelines are silent on this issue. Diphenhydramine is FDA-approved in the treatment of allergic reactions, cough, occasional insomnia, parkinsonism, sneezing due to the common cold, and to prevent motion sickness. The 2008 AASM Guideline and the literature stress the importance of a thorough history in order to establish the type and evolution of insomnia, perpetuating factors, and pertinent concurrent issues. Monitoring data from a sleep diary before and during active treatment is strongly encouraged. Treatment goals should be aimed at improving both the quality and quantity of sleep as well as decreasing daytime impairments. Initial treatment should include at least one behavioral intervention, and all patients should adhere to rules of good sleep hygiene in

combination with other therapies. When long-term treatment with medication is needed, consistent follow up, ongoing assessments of benefit, monitoring for adverse effects, and evaluation of new or exacerbative issues should occur. There was no documented sleep assessment containing any of the elements recommended by the literature, trial of behavioral intervention, or description of benefit with the use of this medication. Further, there was no indication what additional ingredients were contained in this medication or discussion sufficiently supporting the worker's need for these additional ingredients. In the absence of such evidence, the current request for 150mL of Dicopanol (diphenhydramine and other ingredients) 5mg/mL is not medically necessary.

Fanatrex 25 MG/ML Oral Suspension 420 ML #1: 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)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy Drugs (AEDs) Page(s): 16-19.

Decision rationale: Fanatrex (gabapentin and other ingredients) is a medication in the antiepilepsy drug class. The MTUS Guidelines recommend its use for the treatment of neuropathic pain for its efficacy and favorable side effect profile. Documentation should include the change in pain and function at each visit, especially during the dose adjustment phase. The submitted and reviewed records concluded the worker was suffering from cervical sprain; strain/sprain of both elbows, wrists, and knees; plantar fasciitis involving both feet, and right metatarsalgia. The documented pain assessments were minimal and did not include many of the elements recommended by the Guidelines. There was no suggestion the worker was suffering from neuropathic pain. Further, there was no indication what additional ingredients were contained in this medication or discussion sufficiently supporting the worker's need for these additional ingredients. In the absence of such evidence, the current request for 420mL of Fanatrex (gabapentin and other ingredients) 25mg/mL is not medically necessary.