

Case Number:	CM15-0198810		
Date Assigned:	10/16/2015	Date of Injury:	06/25/2009
Decision Date:	12/21/2015	UR Denial Date:	09/11/2015
Priority:	Standard	Application Received:	10/09/2015

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: New York
 Certification(s)/Specialty: Internal 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 49 year old female, who sustained an industrial injury on 06-25-2009. The injured worker is currently able to work with modifications and permanent and stationary. Medical records indicated that the injured worker is undergoing treatment for cervical spine sprain-strain rule out herniated nucleus pulposus, cervical radiculopathy, status post cervical spine surgery, bilateral shoulder sprain-strain rule out internal derangement, bilateral elbow sprain-strain rule out lateral epicondylitis, rule out medial epicondylitis, bilateral wrist sprain-strain rule out internal derangement, and rule out bilateral wrist tenosynovitis. Treatment and diagnostics to date has included cervical spine surgery, physical therapy, and medications. Recent medications have included Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Cyclobenzaprine, Ketoprofen, and compound creams since at least 07-09-2015. Subjective data (07-09-2015 and 08-14-2015), included cervical spine, bilateral shoulder, bilateral elbow, and bilateral wrist pain. Objective findings (08-14-2015) included tenderness to palpation and decreased range of motion to cervical spine, bilateral shoulders, bilateral elbows, and bilateral wrists. The Utilization Review with a decision date of 09-11-2015 non-certified the request for compound cream HMPC2 (Flurbiprofen-Baclofen-Dexamethasone micro-Hyaluronic acid), compound cream HNPC1 (Amitriptyline-Gabapentin-Bupivacaine HCL-Hyaluronic acid), Ketoprofen cream, Cyclobenzaprine cream, Tabradol, Deprizine, Dicopanol, Fanatrex, and extracorporeal shockwave therapy (cervical, bilateral shoulders, elbows, wrists) and modified the request for Synapryn to Synapryn 1 month supply.

IMR ISSUES, DECISIONS AND RATIONALES

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

Compound HMPC2 (Flurbiprofen/Baclofen/Dexamethasone micro/Hyaluronic acid):
Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least one non-recommended drug (or drug class) is not recommended for use. Flurbiprofen is used as a topical NSAID. It has been shown in a meta-analysis to be superior to placebo during the first two weeks of treatment for osteoarthritis but either, not afterward, or with diminishing effect over another two-week period. There are no clinical studies to support the safety or effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic). Baclofen is not recommended as there is currently one Phase III study of Baclofen-Amitriptyline-Ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. Otherwise, there is no peer-reviewed literature to support the use of topical baclofen. There is no documentation in the submitted Medical Records that the injured worker has failed a trial of antidepressants and anticonvulsants. In this injured worker, the medical necessity for the requested topical cream has not been established. Therefore, as per guidelines stated above, the requested treatment: Compound HMPC2 (Flurbiprofen/Baclofen/ Dexamethasone micro/Hyaluronic acid) is not medically necessary.

Compound HNPC1 (Amitriptyline/Gabapentin/Bupivacaine HCL/Hyaluronic acid):
Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example,

NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Gabapentin is not recommended. There is no peer-reviewed literature to support its use. Hyaluronate sodium is a hyaluronic acid derivative, that when injected, works by increasing the effectiveness of the fluid within the knee joint to act as a lubricant and shock absorber. The FDA has also approved this medication for the use in certain eye surgeries. There is no recommendation for its topical use. Guidelines indicate that any compounded product that contains at least one non-recommended drug (or drug class) is not recommended for use. There is no documentation in the submitted Medical Records that the injured worker has failed a trial of antidepressants and anticonvulsants. In this injured worker, the medical necessity for the requested topical cream has not been established. Therefore, as per guidelines stated above, the requested treatment: Compound HNPC1 (Amitriptyline/Gabapentin/Bupivacaine HCL/Hyaluronic acid) is not medically necessary.

Ketoprofen cream: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: The CA MTUS Chronic Pain Guidelines indicate that topical analgesics are "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." They are "largely experimental in use with few randomized controlled trials to determine effectiveness or safety." Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID). The MTUS indicates that topical NSAIDs may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Note that topical Ketoprofen is not FDA approved for topical application. Non-FDA approved medications are not medically necessary. The only FDA-approved topical NSAIDs are diclofenac formulations. All other topical NSAIDs are not FDA approved. The guidelines also indicate that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." The requested treatment: Ketoprofen cream is not medically necessary.

Cyclobenzaprine cream: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control

including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Cyclobenzaprine is a centrally acting skeletal muscle relaxant and is not recommended for topical application. There is no documentation in the submitted Medical Records that the injured worker has failed a trial of antidepressants and anticonvulsants. In this injured worker, the medical necessity for the requested topical cream has not been established. The requested treatment: Cyclobenzaprine cream is not medically necessary.

Synapryn: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids (Classification).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Glucosamine (and Chondroitin Sulfate), Opioids, criteria for use, Opioids for chronic pain.

Decision rationale: Synapryn is combination of tramadol and glucosamine. The reason for combining these medications is not discussed in any physician report. Given that tramadol is generally a prn medication to be used as little as possible, and that glucosamine (assuming a valid indication) is to be taken regularly regardless of acute symptoms, the combination product is not indicated. Tramadol is prescribed without clear evidence of the considerations and expectations found in the MTUS and similar guidelines. Opioids are minimally indicated, if at all, for chronic back pain. The prescribing physician does not specifically address function with respect to prescribing opioids, and does not address the other recommendations in the MTUS. There is no evidence that the treating physician has utilized a treatment plan not using opioids, and that the patient "has failed a trial of non-opioid analgesics". The MTUS provides support for treating moderate arthritis pain, particularly knee OA, with glucosamine sulphate. Other forms of glucosamine are not supported by good medical evidence. The treating physician in this case has not provided evidence of the form of glucosamine in Synapryn, and that it is the form recommended in the MTUS and supported by the best medical evidence. If there is any indication for glucosamine in this case, it must be given as a single agent apart from other analgesics, particularly analgesics like tramadol which are habituating. Synapryn oral suspension is not medically necessary based on the MTUS, lack of good medical evidence, and lack of a treatment plan for chronic opioid therapy consistent with the MTUS.

Tabradol: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

Decision rationale: Tabradol is cyclobenzaprine in an oral suspension. The MTUS for Chronic Pain does not recommend muscle relaxants for chronic pain. Non-sedating muscle relaxants are an option for short term exacerbations of chronic low back pain. This patient has chronic pain

with no evidence of prescribing for flare-ups, and the pain is located in multiple areas. The MTUS states that treatment with cyclobenzaprine should be brief, and that the addition of cyclobenzaprine to other agents is not recommended. In this case, the oral suspension form plus topical is experimental and unproven. Prescribing was not for a short term exacerbation. Per the MTUS, cyclobenzaprine is not indicated. The requested treatment: Tabradol is not medically necessary.

Deprizine: Upheld

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

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

Decision rationale: Deprizine is ranitidine in an oral suspension. There is no documentation indicating the patient has any GI symptoms or GI risk factors. Risk factors include, age >65, history of peptic ulcer disease, GI bleeding, concurrent use of aspirin, corticosteroids, and/or anticoagulants or high-dose/multiple NSAIDs. If ranitidine is prescribed as co-therapy with an NSAID, ranitidine is not the best drug. Co-therapy with an NSAID is not indicated in patients other than those at high risk. No reports describe the specific risk factors present in this case. Medical necessity of the requested item has not been established. The requested treatment: Deprizine is not medically necessary.

Dicopanol: Upheld

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

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, Insomnia Treatment.

Decision rationale: Official Disability Guidelines (ODG) state 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. Dicopanol is diphenhydramine and other proprietary ingredients. Medical necessity cannot be determined for unspecified compounds, and unpublished ingredients cannot be assumed to be safe or effective. Dicopanol is not medically necessary on this basis alone. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. Official Disability Guidelines state that antihistamines are not indicated for long term use as tolerance develops quickly, and that there are many, significant side effects. MTUS states Medications are to be given individually, one at a time, with

assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. Dicopanol is not medically necessary based on lack of a sufficient analysis of the patient's condition, and lack of information provided about the ingredients.

Fanatrex: Upheld

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

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

Decision rationale: Per the MTUS, Fanatrex (gabapentin) is a compounded form of an anti-epilepsy drug (AEDs - also referred to as anti-convulsants). These drugs have been shown to be effective for treatment of diabetic painful neuropathy/polyneuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. FDA-approved drugs should be given adequate trial, if these are inadequate, ineffective or contraindicated in the individual patient, then compounded drugs with FDA-approved ingredients can be considered. The clinical documentation submitted for review does not indicate diagnoses of diabetic neuropathy or postherpetic neuralgia. Painful neuropathic symptoms were noted; however, there is no indication for the compounded oral suspension form of this drug in such a low dose (non-therapeutic dose) in comparison to the recommended dose of oral gabapentin in tablet form. In addition, there is no documented failed trial of the FDA-approved form of this drug, and no indication as to the reason that the FDA-approved form is contraindicated in the injured worker. As such, the request for Fanatrex is not medically necessary.

Extracorporeal shockwave therapy 3x/6 (cervical, bilateral shoulders/elbows/wrist): Upheld

Claims Administrator guideline: Decision based on MTUS Neck and Upper Back Complaints 2004.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Neck and Upper Back Chapter, Low Back Chapter--Extracorporeal shock wave therapy (ESWT) and Other Medical Treatment Guidelines Journal of Orthopaedic Surgery and Research 7.1 (2012) pages 1-8, Up-to-date-Extracorporeal shockwave therapy.

Decision rationale: Extracorporeal shock wave therapy (ESWT) is not recommended for back pain. The available evidence does not support the effectiveness of shock wave for treating back pain. In the absence of such evidence, the clinical use of these forms of treatment is not justified and should be discouraged. Two small studies have been published for upper back or neck pain. In this study trigger point treatment with radial shock wave used in combination with physical therapy provided temporary relief of neck and shoulder pains, but the effects of radial shock wave without physical therapy need to be examined in further studies. Extracorporeal shockwave therapy is primarily used for sports-related overuse tendinopathies that include

plantar fasciitis, lateral epicondylitis, shoulder and patellar tendinopathy. The injured worker's diagnoses include sprain/strain of shoulders, elbows and wrists. This injured worker's injury is not noted to be from overuse. Also this procedure is not recommended for hand/wrist. Based on the currently available medical information for review, medical necessity of the requested treatment has not been established. The Requested Treatment: Extracorporeal shockwave therapy 3x/6 (cervical, bilateral shoulders/elbows/wrist) is not medically necessary and appropriate.