

Case Number:	CM14-0018395		
Date Assigned:	04/18/2014	Date of Injury:	11/04/2013
Decision Date:	10/03/2014	UR Denial Date:	02/06/2014
Priority:	Standard	Application Received:	02/13/2014

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. The expert reviewer is Board Certified in Physical Medicine & Rehabilitation, has a subspecialty in Interventional Spine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 65 year old female with date of injury 11/4/13. The treating physician report dated 1/13/14 indicates that the patient presents with left shoulder pain radiating down the arm to the fingers. The pain is rated a 7-8/10 and is constant. The current diagnoses are: 1. Rotator cuff of the left shoulder 2. Joint derangement. The utilization review report dated 2/5/14 denied the request for Synapryn, Tramadol, Dicopanol and TENS unit based on lack of guideline support.

IMR ISSUES, DECISIONS AND RATIONALES

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

SYNAPRYN 10MG/ML, 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 SYNAPRYN Page(s): 111.

Decision rationale: The patient presents with left shoulder pain radiating down the arm to the fingers. The current request is for Synapryn 20mg/ml, 500ml. The treating physician has prescribed Synapryn for neuropathic/fibromyalgia pain. Synapryn is an oral suspension that contains Tramadol and Glucosamine as well as other proprietary ingredients. MTUS in general

for compounded medications, page 111 states "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." The "other proprietary ingredients" are not disclosed. Since components of "other proprietary ingredients" are unknown, they cannot be compared against MTUS criteria, and therefore cannot be confirmed to be in accordance with MTUS. Recommendation is for denial.

TABRADOL 1MG/ML, 250ML: 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=20057](http://DAILYMED.NLM.NIH.GOV/DAILYMED/DRUGINFO.CFM?ID=20057)

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

Decision rationale: The patient presents with left shoulder pain radiating down the arm to the fingers. The current request is for Tabradol 1mg/ml, 250ml. In review of the treating physician report dated 1/13/14 the physician states, "Tabradol contains Cyclobenzaprine, Methyl Sulfony Methane and other proprietary ingredients. Though Methyl Sulfony Methane is regarded as a dietary supplement and is regulated by the FDA, it has not been approved for the treatment of osteoarthritis." The MTUS guidelines support the usage of Cyclobenzaprine for a short course of therapy, not longer than 2-3 weeks. The physician in this case has not documented that this medication will be used for 2-3 weeks. MTUS in general for compounded medications, page 111 states "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." The "other proprietary ingredients" are not disclosed. Since components of "other proprietary ingredients" are unknown, they cannot be compared against MTUS criteria, and therefore cannot be confirmed to be in accordance with MTUS. Recommendation is for denial.

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 PDR (PHYSICIAN'S DESK REFERENCE)
[HTTP://WWW.DRUGS.COM/PRO/DIPHENHYDRAMINE.HTML#IXZZ0XZIFCBWP](http://WWW.DRUGS.COM/PRO/DIPHENHYDRAMINE.HTML#IXZZ0XZIFCBWP)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Dicopanol Page(s): 111. Decision based on Non-MTUS Citation ODG guidelines, Pain chapter online for Insomnia treatment

Decision rationale: The patient presents with left shoulder pain radiating down the arm to the fingers. The current request is for Dicopanol 5mg/ml, 150ml. There is no information in the treating physician report that indicates the patient has complaints of insomnia and there is no diagnosis of insomnia. The physician states, "Dicopanol contains Diphenhydramine and other proprietary ingredients. Many pharmacological agents currently on the market for the treatment of insomnia include benzodiazepines and non-benzodiazepines hypnotics. Diphenhydramine is widely used in many non-prescription sleep aids and cold medications for many years. It has

been shown to be safe and effective in the treatment of mild to moderate insomnia." MTUS in general for compounded medications, page 111 states "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." The "other proprietary ingredients" are not disclosed. Since components of "other proprietary ingredients" are unknown, they cannot be compared against MTUS criteria, and therefore cannot be confirmed to be in accordance with MTUS. In this case the physician has failed to document that this patient has insomnia, and the prescribed medication for insomnia is not supported by MTUS. ODG guidelines do not support Diphenhydramine on a long-term basis for insomnia either. Recommendation is for denial.

TENS UNIT: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Transcutaneous electrotherapy; TENS, chronic pain (transcutaneous electrical nerve stimulation);

Decision rationale: The patient presents with left shoulder pain radiating down the arm to the fingers and is 10 weeks post injury. The current request is for TENS unit. The treating physician does not indicate if the request is for purchase or for a rental trial of TENS unit. The MTUS guidelines state: A one-month trial period of the TENS unit should be documented (as an adjunct to ongoing treatment modalities within a functional restoration approach) with documentation of how often the unit was used, as well as outcomes in terms of pain relief and function; rental would be preferred over purchase during this trial. The treating physician has failed to document if the request is for a trial or purchase of a TENS unit. MTUS criteria for a TENS unit trial states, Documentation of pain of at least three months duration. The patient is only 10 weeks post injury and the request is not supported by MTUS. Recommendation is for denial.

Ketoprofen 20% in PLO gel, 120 gm.: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Non-steroidal antiinflammatory agents (NSAIDs) Capsaicin Baclofen Other mu.

Decision rationale: [REDACTED] 1/13/14 report states that the patient complains of left shoulder pain radiating down the arm to the fingers. The pain is rated a 7-8/10 and is constant. The request is for Ketoprofen 20% in PLO gel, 120grams, Cyclophen %5 in PLO gel, 120 grams. According to MTUS guidelines, Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. MTUS page 111 states the following: Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. (Diaz, 2006) (Hindsen, 2006) Absorption of the drug depends on the base it is delivered in. (Gurol, 1996). Topical treatment can result in blood concentrations and systemic effect comparable to those

from oral forms, and caution should be used for patients at risk, including those with renal failure. Since Ketoprofen is not recommended, the whole compound is not within MTUS guidelines. Recommendation is for denial.

Cyclophen 5% in PLO gel, 120 gm: 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 Topical Analgesics Non-steroidal antiinflammatory agents (NSAIDs) Capsaicin Baclofen Other mu.

Decision rationale: [REDACTED] 1/13/14 report states that the patient complains of left shoulder pain radiating down the arm to the fingers. The pain is rated a 7-8/10 and is constant. The request is for Ketoprofen 20% in PLO gel, 120grams, Cyclophen %5 in PLO gel, 120 grams. According to MTUS guidelines, Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. MTUS page 111 states the following: Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. (Diaz, 2006) (Hindsen, 2006) Absorption of the drug depends on the base it is delivered in. (Gurol, 1996). Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. Since Ketoprofen is not recommended, the whole compound is not within MTUS guidelines. Recommendation is for denial.

physical therapy twice weekly for 6 weeks (body part unspecified): 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 Chronic Pain Medical Treatment Guidelines MTUS Physical Medicine Physical Medicine Guidelines.

Decision rationale: [REDACTED] 1/13/14 report states that the patient complains of left shoulder pain radiating down the arm to the fingers. The pain is rated a 7-8/10 and is constant. The request is for physical therapy 2 times 6 for the left shoulder. MTUS guidelines pages 98, 99 states that for Myalgia and Myositis, 9-10 visits are recommended over 8 weeks. For Neuralgia, neuritis, and radiculitis, 8-10 visits are recommended. In this case, the physician has asked for 12 total sessions of therapy for the patient's left shoulder. A short course of treatment may be reasonable if the patient is flared-up, has a new injury or aggravated. However, such documentations are not provided and the request of 12 sessions exceeds what is allowed per MTUS. Recommendation is for denial.

acupuncture - left shoulder thrice weekly for 6 weeks: 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 Chronic Pain Medical Treatment Guidelines Acupuncture for Neck and Low back Pain:<http://www..>

Decision rationale: [REDACTED] 1/13/14 report states that the patient complains of left shoulder pain radiating down the arm to the fingers. The pain is rated a 7-8/10 and is constant. The request is for Acupuncture 3 times 6 for the left shoulder. Review of the reports does not show any history of acupuncture. MTUS allows for a trial of acupuncture up to 6 sessions and more if functional improvement is demonstrated. The request for a total of 18 acupuncture sessions exceeds what is allowed by MTUS for an initial trial. Recommendation is for denial.

shockwave - left shoulder, up to 3 treatments: 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 Chronic Pain Medical Treatment Guidelines Recommended for calcifying tendinitis but not for othe.

Decision rationale: [REDACTED] 1/13/14 report states that the patient complains of left shoulder pain radiating down the arm to the fingers. The pain is rated a 7-8/10 and is constant. The request is for shockwave, up to 3 treatments for the left shoulder. MTUS guidelines state that shockwave therapy is Recommended for calcifying tendinitis but not for other shoulder disorders. There is no indication that the patient has calcifying tendinitis; therefore, recommendation is for denial.

functional capacity evaluation: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Chronic Pain Medical Treatment Guidelines ACOEM guidelines, Chapter 7, p137-139 has the following regarding functional capacity evaluations:

Decision rationale: [REDACTED] 1/13/14 report states that the patient complains of left shoulder pain radiating down the arm to the fingers. The pain is rated a 7-8/10 and is constant. The request is for a functional capacity evaluation. MTUS does not discuss functional capacity evaluations. ACOEM chapter 7, was not adopted into MTUS, but would be the next highest-ranked standard according to LC4610.5 (2) (B). ACOEM does not appear to support the functional capacity evaluations and states: "Functional capacity evaluations may establish physical abilities, and also facilitate the examinee/employer relationship for return to work. However, FCEs can be deliberately simplified evaluations based on multiple assumptions and subjective factors, which are not always apparent to their requesting physician. There is little

scientific evidence confirming that FCEs predict an individual's actual capacity to perform in the workplace; an FCE reflects what an individual can do on a single day, at a particular time, under controlled circumstances, that provide an indication of that individual's abilities. As with any behavior, an individual's performance on an FCE is probably influenced by multiple nonmedical factors other than physical impairments. For these reasons, it is problematic to rely solely upon the FCE results for determination of current work capability and restrictions." There is no discussion regarding the patient's work status. The functional capacity evaluation does not appear to be in accordance with ACOEM guidelines. Recommendation is for denial.

MRI study - left shoulder: Overturned

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints Page(s): 207-208.

Decision rationale: [REDACTED] 1/13/14 report states that the patient complains of left shoulder pain radiating down the arm to the fingers. The pain is rated a 7-8/10 and is constant. The request is for an MRI of the left shoulder. There is no indication that the patient had a recent MRI of her left shoulder. ACOEM guidelines states: Unequivocal objective findings that identify specific nerve compromise on the neurologic examination are sufficient evidence to warrant imaging in patients who do not respond to treatment and who would consider surgery an option. ODG guidelines do not support MRI's unless there are neurologic signs/symptoms are present. The patient presents with positive exam findings for the left shoulder impingement and given that there is no mention of prior MRI, an MRI would appear reasonable and consistent with ODG guidelines. Recommendation is for authorization.

EMG study - left upper extremity: Overturned

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 11 Forearm, Wrist, and Hand Complaints Page(s): 262.

Decision rationale: [REDACTED] 1/13/14 report states that the patient complains of left shoulder pain radiating down the arm to the fingers. The pain is rated a 7-8/10 and is constant. The request is for an EMG for the left upper extremity. There is no indication of whether the patient previously had an EMG conducted. For EMG, ACOEM Guidelines page 262 states, "Appropriate electrodiagnostic studies may help differentiate between CTS and other conditions such as cervical radiculopathy. They may include nerve conduction studies or in more difficult cases, electromyography may be helpful. NCS and EMG may confirm the diagnosis of CTS, but may be normal in early or mild cases of CTS. If the EDS are negative, test may be repeated later in the course of treatment if symptoms persist." An EMG may help the physician pinpoint the cause and location of the patient's symptoms. Recommendation is for authorization.

NCV study - left upper extremity: Overturned

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 11 Forearm, Wrist, and Hand Complaints Page(s): 262.

Decision rationale: [REDACTED] 1/13/14 report states that the patient complains of left shoulder pain radiating down the arm to the fingers. The pain is rated a 7-8/10 and is constant. The request is for NCV for the left upper extremity. There is no indication of whether the patient previously had a NCV conducted. For EMG, ACOEM Guidelines page 262 states, "Appropriate electrodiagnostic studies may help differentiate between CTS and other conditions such as cervical radiculopathy. They may include nerve conduction studies or in more difficult cases, electromyography may be helpful. NCS and EMG may confirm the diagnosis of CTS, but may be normal in early or mild cases of CTS. If the EDS are negative, test may be repeated later in the course of treatment if symptoms persist." A NCV may help the physician pinpoint the cause and location of the patient's symptoms. Recommendation is for authorization.

Terocin Patch (quantity unspecified): 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 Topical Analgesics Page(s): 111.

Decision rationale: [REDACTED] 1/13/14 report states that the patient complains of left shoulder pain radiating down the arm to the fingers. The pain is rated a 7-8/10 and is constant. The request is for Terocin Patch. Terocin patches are a dermal patch with 4% Lidocaine, and 4% menthol. MTUS for topical Lidocaine states: "Indication: Neuropathic pain Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as Gabapentin or Lyrica)." And "Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain." In this patient, while the patient has pain down the arm to the fingers, the neuropathic pain is not localized. There is no evidence that this patch is being used for neuropathic pain. Recommendation is for denial.