

Case Number:	CM15-0052663		
Date Assigned:	03/26/2015	Date of Injury:	11/09/2011
Decision Date:	05/14/2015	UR Denial Date:	03/18/2015
Priority:	Standard	Application Received:	03/19/2015

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, Arizona

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 50-year-old male who reported injury on 11/09/2011. The mechanism of injury was not provided. Prior therapy included acupuncture and chiropractic treatment. The documentation of 02/02/2015 revealed the injured worker had mild to moderate improvement in symptoms with conservative therapy and medications. The physical examination revealed a normal gait. The injured worker had tenderness to palpation with spasm of the upper trapezius muscles on the right. The injured worker had tenderness to palpation with spasms of the paraspinals on the right on the thoracic spine. The injured worker had tenderness to palpation in the right medial epicondyle and right upper trapezius muscles and tenderness to palpation in the right glenohumeral joint. The diagnoses included right shoulder arthralgia, thoracic spine musculoligamentous sprain and strain, thoracic spine myospasm, right elbow arthralgia, rule out medial epicondylitis, and left index finger pain. The treatment plan included chiropractic including physiotherapy and acupuncture 2 times a week time 6 weeks, x-rays for the thoracic spine, right shoulder, and right elbow, a TENS/multistem/ interferential unit and a hot and cold wrap or thermal combo unit for home use, and medications including Naproxen 550 mg 1 by mouth twice a day as needed, Protonix 1 capsule by mouth twice a day as needed, and Flexeril 1 tablet by mouth twice a day as needed as well as transdermal compounds and a urine toxicology screen.

IMR ISSUES, DECISIONS AND RATIONALES

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

Xray Right Shoulder: Upheld

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): 207-209.

Decision rationale: The American College of Occupational and Environmental Medicine indicate that for most injured workers with shoulder problems special studies are not needed unless a 4 to 6 week period of conservative care and observation fails to improve symptoms. Routine testing including x-rays and more specialized imaging studies are not recommended during the first month to 6 weeks of activity and limitation. The clinical documentation submitted for review failed to provide documentation of a failure of conservative care directed at the shoulder. There was a lack of documentation of exceptional factors to warrant nonadherence of guidelines recommendations. There were no objective findings upon physical examination to support the necessity for an x-ray. The request as submitted failed to indicate the shoulder to be x-rayed. Given the above, the request for x-ray shoulder is not medically necessary.

TENS (transcutaneous electrical nerve stimulation)/Multi Stim Interferential Unit, for purchase: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Transcutaneous electrotherapy; TENS, chronic pain; Neuromuscular electrical stimulation (NMES devices) Page(s): 114-116, 121.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TENS, NMES, Interferential Current Stimulation Page(s): 114-116, 121, 118.

Decision rationale: The California Medical Treatment Utilization Schedule recommends a one month trial of a TENS unit as an adjunct to a program of evidence-based functional restoration for chronic neuropathic pain. Prior to the trial there must be documentation of at least three months of pain and evidence that other appropriate pain modalities have been tried (including medication) and have failed. They do not recommend Neuromuscular electrical stimulation (NMES devices) as there is no evidence to support its use in chronic pain. They do not recommend Interferential Current Stimulation (ICS) as an isolated intervention. There was a lack of documentation of exceptional factors to warrant nonadherence of guidelines recommendations. There was a lack of documentation of objective pain relief and objective functional improvement from a trial of the unit. Given the above, the request for TENS (transcutaneous electrical nerve stimulation)/multi stim interferential unit, for purchase is not medically necessary.

Xray Thoracic Spine: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 177-179.

Decision rationale: The American College of Occupational and Environmental Medicine indicate for most injured workers with true neck or upper back problems special studies are not need unless a 3 to 4 week period of conservative care and observation fails to improve symptoms. The clinical documentation submitted review failed to provide the duration of conservative care. There was a lack of documentation indicating the specific conservative care directed toward the thoracic spine. There was a lack of documentation of exceptional factors. Given the above, the request for x-ray thoracic spine is not medically necessary.

Naproxen 550 mg Qty 60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-68, 73.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 67.

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines indicate that NSAIDS are recommended for short term symptomatic relief of mild to moderate pain. There should be documentation of objective functional improvement and an objective decrease in pain. The clinical documentation submitted for review indicated the injured worker had utilized the medication. There was a lack of documentation of objective functional improvement and an objective decrease in pain. The request as submitted failed to indicate the frequency for the medication. Additionally, there was a lack of documentation indicating a necessity for both a topical and oral form of the medication. Given the above the request for Naproxen 550 mg Qty 60 is not medically necessary.

Flexeril 7.5 mg Qty 60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63-64.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63.

Decision rationale: The California Medical Treatment Utilization Schedule guidelines recommend muscle relaxants as a second line option for the short term treatment of acute low back pain and their use is recommended for less than 3 weeks. There should be documentation of objective functional improvement. The clinical documentation submitted review indicated the injured worker had utilized the medication. There was lack documentation of objective findings of muscle spasms to support the necessity for the medication. Additionally, as this is recommended for a short term, this medication would not be supported. The request as submitted failed to indicate the frequency for the requested medication. There was a lack of documentation indicating a necessity for multiple topicals and oral forms of the requested medication. Given the above, the request for Flexeril 7.5 mg Qty 60 is not medically necessary.

Protonix 20 mg Qty 60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 69.

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines recommend proton pump inhibitors for injured workers at intermediate risk or higher for gastrointestinal events. The clinical documentation submitted for review failed to provide documentation the injured worker was at intermediate risk or higher risk for gastrointestinal events. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Protonix 20 mg Qty 60 is not medically necessary.

Gabapentin 15% Amitriptyline 4% Dextromethorphan 10% 180gm: 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, Antidepressants, Topical Antiepileptic Medications, does not address topical dextromethorphan or topical antidepressants Page(s): 111, 13, 113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) do not address topical dextromethorphan or topical antidepressants; Skolnick P (1999) Antidepressants for the new millennium. Eur J Pharmacol 375:31-40.<http://www.drugs.com/dextromethorphan.html>.

Decision rationale: The California Medical Treatment Utilization Schedule guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended Peer reviewed literature states that while local peripheral administration of antidepressants has been demonstrated to produce analgesia in the formalin model of tonic pain; a number of actions, to include inhibition of noradrenaline (NA) and 5-HT reuptake, inhibition of NMDA, nicotinic, histamine, and 5-HT receptors, and block of ion channels and even combinations of these actions, may contribute to the local peripheral efficacy of antidepressant; therefore the contribution of these actions to analgesia by antidepressants, following either systemic or local administration, remains to be determined. Per Drugs.com, "Dextromethorphan is a cough suppressant. It affects the signals in the brain that trigger cough reflex." The clinical documentation submitted for review failed to provide documentation the injured worker had a trial and failure of antidepressants and anticonvulsants. There was a lack of documentation indicating a necessity and a rationale for dextromethorphan in the compound. There was a lack of documentation indicating a necessity for multiple medications with a topical antidepressant and anti-epilepsy medications. Additionally, the request as submitted failed to indicate the frequency and body part to be treated. Given the above the request for Gabapentin 15% Amitriptyline 4% Dextromethorphan 10% 180gm is not medically necessary.

Capsaicin 0.025% Flurbiprofen 15% Gabapentin 10% 180 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 Flurbiprofen, Topical analgesics, Topical Capsaicin, Gabapentin Page(s): 72, 111, 28, 113.

Decision rationale: The California Medical Treatment Utilization Schedule guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. Flurbiprofen is classified as a non-steroidal anti-inflammatory agent. This agent is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institute of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments Gabapentin: Not recommended. There is no peer-reviewed literature to support use. The clinical documentation submitted review failed to provide documentation of a failure of antidepressants and anticonvulsants. There was a lack of documentation indicating a necessity for multiple topical and oral NSAIDs and multiple anti-epilepsy medication formulations. There was a lack of documentation of exceptional factors to warrant nonadherence to guideline recommendations. The request as submitted failed to indicate the frequency and the body part to be treated. Given the above, the request for Capsaicin 0.025% Flurbiprofen 15% Gabapentin 10% 180 gm is not medically necessary.

Cyclobenzaprine 2% Gabapentin 15% Amitriptyline 10% 180 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, Antidepressants, Topical Antiepileptic Medications, Capsaicin, does not address topical antidepressants Page(s): 111, 13, 28, 113. Decision based on Non-MTUS Citation Skolnick P (1999) Antidepressants for the new millennium. Eur J Pharmacol 375:31-40.

Decision rationale: The California Medical Treatment Utilization Schedule guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended Peer reviewed literature states that while local peripheral administration of antidepressants has been demonstrated to produce analgesia in the formalin model of tonic pain; a number of actions, to include inhibition of noradrenaline (NA) and 5-HT reuptake, inhibition of NMDA, nicotinic, histamine, and 5-HT receptors, and block of ion channels and even combinations of these actions, may contribute to the local peripheral efficacy of antidepressant; therefore the contribution of these actions to

analgesia by antidepressants, following either systemic or local administration, remains to be determined. Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. The clinical documentation submitted review failed to provide documentation of a failure of antidepressants and anticonvulsants. There was a lack of documentation indicating a necessity for multiple formulations of cyclobenzaprine. There was a lack of documentation indicating a necessity for multiple topical medications with both gabapentin and amitriptyline. The request as submitted failed to indicate the frequency and body part to be treated. Given the above the request for Cyclobenzaprine 2% Gabapentin 15% Amitriptyline 10% 180 gm is not medically necessary.

Cyclobenzaprine 2% Flurbiprofen 25% 180 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, Capsaicin, Flurbiprofen Page(s): 111, 28, 72.

Decision rationale: The California Medical Treatment Utilization Schedule guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. Regarding Topical Flurbiprofen FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institute of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. The clinical documentation submitted for review failed to provide documentation of a trial and failure of antidepressants and anticonvulsants. There was a lack of documentation indicating a necessity for multiple topical and oral formulations for cyclobenzaprine. There was a lack of documentation indicating a necessity for multiple formulations of NSAIDs. The request as submitted failed to indicate the frequency for the requested medication as well as the body part to be treated. Given the above, the request for Cyclobenzaprine 2% Flurbiprofen 25% 180 gm is not medically necessary.

