

Case Number:	CM15-0014806		
Date Assigned:	02/02/2015	Date of Injury:	09/29/2012
Decision Date:	06/01/2015	UR Denial Date:	01/12/2015
Priority:	Standard	Application Received:	01/26/2015

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 49-year-old male who reported injury on 09/29/2012. The mechanism of injury was noted to be a fight with bar patrons. The injured worker underwent a left shoulder arthroscopy with partial synovectomy and chondroplasty on 02/07/2014. The documentation of 12/16/2014 revealed the injured worker had constant cervical spine pain, low back pain and intermittent left shoulder pain. There was a complaint of loss of sleep due to pain. The injured worker had decreased range of motion in the cervical spine and lumbar spine in abduction, extension and flexion. Cervical compression caused pain. There were noted to be psychological complaints. The diagnoses included cervical disc protrusion, lumbar disc protrusion, lumbar radiculopathy, left shoulder bursitis, infraspinatus, subscapularis and supraspinatus tendinosis, loss of sleep, and depression. The treatment plan included a new EMG/NCV of the bilateral upper and lower extremities. There was a Request for Authorization submitted for review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbiprofen 20%, Tramadol 20% base 30gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen, Topical analgesics, Tramadol Page(s): 72, 111, 82.

Decision rationale: The California Medical Treatment Utilization Schedule indicates topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. 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. A thorough search of FDA.gov, did not indicate there was a formulation of topical Tramadol that had been FDA approved. The approved form of Tramadol is for oral consumption, which is not recommended as a first line therapy. As Tramadol is a form of an opiate, the California Medical Treatment Utilization Schedule chronic pain guidelines recommend opiates for chronic pain. There should be documentation of an objective improvement in function, an objective decrease in pain, and evidence that the patient is being monitored for aberrant drug behavior and side effects. There was a lack of documentation indicating the injured worker had a trial and failure of antidepressants and anticonvulsants. There was a lack of documentation of an objective improvement in function, an objective decrease in pain, and evidence that the patient is being monitored for aberrant drug behavior and side effects. There was a lack of documentation of exceptional factors to warrant non-adherence 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 Flurbiprofen 20%, Tramadol 20% base 30gm is not medically necessary.

Gabapentin 10%, Deximethorphan 10%/ Amitriptyline 10% In Mediderm base 30 gm:
Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Antidepressants, Topical Antiepileptic Medications, Topical Capsaicin, Topical Analgesics, Topical Salicylates, antidepressants Page(s): 111, 13, 113, 28, 111, 105. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence:

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 following is the mediderm base. 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. Topical Salicylates are recommended. Capsaicin is 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. There was a lack of documentation indicating the injured worker had a trial and failure of antidepressants and anticonvulsants. 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. There was a lack of documented rationale to support the use of multiple topical medications with antiepilepsy medications, and antidepressants. The rationale for inclusion of Dextromethorphan was not provided. Given the above, the request for Gabapentin 10%, Dextromethorphan 10%/ Amitriptyline 10% In Mediderm base 30 gm is not medically necessary.

Gabapentin 10%/Amitriptyline 10%/Bupivacaine 5% in cream base- 210 gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Antidepressants, Topical Antiepileptic Medications, Bupivacaine Page(s): 111, 13, 113, 55. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: 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. Bupivacaine has been recommended as an alternative to clonidine, however a search of FDA guidelines indicate that Bupivacaine is approved for injection. There was a lack of documentation indicating the injured worker had a trial and failure of antidepressants and anticonvulsants. 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. There was a lack of documented rationale to support the use of multiple topical medications with antiepilepsy medications, and antidepressants. The rationale for inclusion of Dextromethorphan was not provided. Given the above, the request Gabapentin 10%/Amitriptyline 10%/Bupivacaine 5% in cream base- 210 gm is not medically necessary.

Flurbiprofen 20%, Baclofen 5%, Dexamethasone 2%, Menthol 2%- C Amphor 2%, Capsaicin 0.025% in Cream Base 210 gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Salicylate Topicals, Flurbiprofen, Capsaicin, Baclofen Page(s): 111, 105, 72, 25, 113. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/search.php?searchterm=dexamethasone&a=1>.

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. 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. 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. Salicylate Topicals are recommended. There is no peer-reviewed literature to support the use of topical baclofen. Per Drugs.com, "Dexamethasone is a corticosteroid that prevents the release of substances in the body that cause inflammation. Dexamethasone is used to treat many different inflammatory conditions such as allergic disorders, skin conditions, ulcerative colitis, arthritis, lupus, psoriasis, or breathing disorders." Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. There was a lack of documentation indicating the injured worker had a trial and failure of

antidepressants and anticonvulsants. 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. There was a lack of documented rationale to support the use of multiple topical medications with Flurbiprofen. There was a lack of documentation that the injured worker was intolerant of other treatments. Given the above, the request Flurbiprofen 20%, Baclofen 5%, Dexamethasone 2%, Menthol 2% - Camphor 2%, Capsaicin 0.025% in Cream Base 210 gm is not medically necessary.