

Case Number:	CM15-0062252		
Date Assigned:	04/08/2015	Date of Injury:	05/07/2013
Decision Date:	06/02/2015	UR Denial Date:	03/10/2015
Priority:	Standard	Application Received:	04/02/2015

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

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & General Preventive 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 50-year-old female, who sustained an industrial injury on May 7, 2013, incurring neck and back injuries. The mechanism of injury was not provided. Treatment included a TENS unit, physical therapy, trigger point injections cervical epidural steroid injection, and pain management. Currently, the injured worker complained of severe neck pain, limited range of motions to the neck and left arm, spasms and tingling and numbness in the cervical region. The treatment plan that was requested for authorization included a cervical epidural steroid injection under fluoroscopy guidance, and prescriptions for ten Duragesic patches, Lyrica, Flurbiprofen, Capsaicin in Lidopro base cream, Gabapentin, Ketoprofen, Tramadol, Cyclobenzaprine in activemax base and thirty Terocin patches.

IMR ISSUES, DECISIONS AND RATIONALES

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

1 SECOND CESI INJECTION AT C7-T1 WITH CATHETER TO C6-7 UNDER FLUOROSCOPY GUIDANCE: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Epidural Steroid Injection Page(s): 46.

Decision rationale: The California MTUS Guidelines recommend repeat epidural steroid injections when there is documentation of at least 50% pain relief with documentation of objective functional improvement and an objective decrease in pain medications for 6 to 8 weeks. The clinical documentation submitted for review indicated the injured worker had 50% improvement after the first cervical epidural steroid injection. The injured worker was noted to have improvement in weakness, tingling, and numbness in the bilateral upper extremities. However, there was a lack of documentation of objective functional benefit. There was a lack of documentation indicating an objective decrease in pain per the VAS scale and in pain medications for 6 to 8 weeks. Given the above, the request for 1 second CESI injection at C7-T1 with catheter to C6-7 under fluoroscopy guidance not medically necessary.

10 DURAGESIC PATCH 50 MCG: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic pain, ongoing management Page(s): 60,78.

Decision rationale: The California MTUS 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 injured worker is being monitored for aberrant drug behavior and side effects. The clinical documentation submitted for review failed to indicate the injured worker had objective functional improvement, an objective decrease in pain, and documentation the injured worker was being monitored for side effects. The injured worker was being monitored for aberrant drug behavior. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for 10 duragesic patch 50 mcg is not medically necessary.

90 LYRICA 50MG BETWEEN 2/18/2015 AND 4/23/2015: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITIES GUIDELINES.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepileptic Drugs Page(s): 16.

Decision rationale: The California MTUS guidelines recommend antiepilepsy medications as a first line medication for treatment of neuropathic pain. There should be documentation of an objective decrease in pain of at least 30% to 50% and objective functional improvement. The clinical documentation submitted for review failed to provide documentation of 30% to 50% pain relief and documentation of objective functional benefit. The request as submitted failed to

indicate the frequency for the requested medication. Given the above, the request for 90 Lyrica 50mg between 2/18/2015 and 4/23/2015 is not medically necessary.

FLURBIPROFEN 25% CAPSAICIN 0.025% IN LIPODERM BASE 180 GM BETWEEN 2/18/2015 AND 4/23/2015: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Salicylate Topicals, Flurbiprofen, Capsaicin Page(s): 111, 105, 72, 25. Decision based on Non-MTUS Citation www.pccarx.com/pcca-products/pcca-exclusives/bases/lipoderm.

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. Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. Per PCCA, "Lipoderm is a quick-absorbing transdermal that delivers up to four drugs at once." 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 indicating the injured worker had osteoarthritis. There was a lack of documentation indicating the injured worker had not responded or was intolerant to other treatments. There was a lack of documentation indicating a necessity for 2 topical NSAIDs. The request as submitted failed to indicate the body part and frequency for the requested medication. Given the above, the request for flurbiprofen 25% capsaicin 0.025% in lipoderm base 180 gm between 2/18/2015 and 4/23/2015 is not medically necessary.

GABAPENTIN 10%, KETOPROFEN 10%, TRAMADAL 5%, CYCLOBENZAPRINE 2%, IN ACTIVEMAX BASE 180 MG BETWEEN 2/18/2015 AND 4/23/2015: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Gabapentin, Topical Cyclobenzaprine, Ketoprofen, Tramadol Page(s): 111, 113, 112, 82. Decision based on Non-MTUS Citation www.pccarx.com/pcca-products/pcca-exclusives/bases/lipoderm.

Decision rationale: The California Medical Treatment Utilization Schedule guidelines indicates that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety and any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended and 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. Gabapentin: Not recommended. There is no peer-reviewed literature to support use do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. The addition of cyclobenzaprine to other agents is not recommended. Ketoprofen is not currently FDA approved for a topical application. 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. Per PCCA, "Lipoderm is a quick-absorbing transdermal that delivers up to four drugs at once." The clinical documentation submitted for review failed to provide documented rationale for the use of the medication. 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. The request as submitted failed to indicate the frequency for the requested medication and the body part to be treated. There was a lack of documentation indicating a necessity for 2 topical creams with NSAIDs. Given the above, the request for gabapentin 10%, ketoprofen 10%, tramadol 5%, cyclobenzaprine 2%, in Activemax base 180 mg between 2/18/2015 and 4/23/2015 is not medically necessary.

30 TEROGIN PATCHES BETWEEN 2/15/2015 AND 4/23/2015: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals, Topical Analgesic, Lidocaine Page(s): 105, 111, 112. Decision based on Non-MTUS Citation dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=100ceb76-8ebe-437b-a8de-37cc76ece9bb.

Decision rationale: The California Medical Treatment Utilization Schedule guidelines indicate that topical analgesics are largely experimental in use with few randomized control 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. The guidelines indicate that topical lidocaine (Lidoderm) may be 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). No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. The guidelines

recommend treatment with topical salicylates. Per dailymed.nlm.nih.gov, Terocin patches are topical Lidocaine and Menthol. 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 of exceptional factors to warrant non-adherence to guideline recommendations. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for 30 terocin patches between 2/15/2015 and 4/23/2015 is not medically necessary.