MAXIMUS Federal Services

Case Number:	CM15-0055831		
Date Assigned:	04/01/2015	Date of Injury:	04/15/2005
Decision Date:	05/14/2015	UR Denial Date:	03/12/2015
Priority:	Standard	Application Received:	03/24/2015

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: 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 64-year-old male who reported injury on 04/15/2005. The diagnoses were unspecified essential hypertension; nonorganic sleep disorder, unspecified; and chronic obstructive asthma, unspecified. The mechanism of injury was lifting. The most recent documentation submitted for review was dated 03/05/2015. The documentation indicated the injured worker was scheduled for surgery on 03/09/2015. The injured worker was staying on his medications and had been utilizing his CPAP machine. The injured worker had headaches with no chest pain. The physical examination revealed no cyanosis, clubbing, or edema; no calf tenderness; and the pulses were normal. The blood pressure was 104/66. The documentation indicated the treatment plan included a continuation of transdermal medications.

IMR ISSUES, DECISIONS AND RATIONALES

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

Terocin Patches, QTY: 30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patch); Topical Analgesics.

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 Other Medical Treatment Guideline or Medical Evidence: http://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 as to a necessity for both a topical lotion and a topical patch formulation for Terocin patches. There was a lack of documentation indicating the injured worker had trialed and failed antidepressants and anticonvulsants. There was a lack of documentation of exceptional factors to warrant nonadherence to guideline recommendations. The documentation indicated the injured worker would continue the topical and transdermal. 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 requested topical patch. Given the above, the request for Terocin patches, quantity 30, is not medically necessary.

Terocin 240mL cream: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111, 112.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals, Topical Analgesic, Topical Capsaicin, Lidocaine Page(s): 105, 111, 28, 112. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: http://www.drugs.com/search.php?searchterm=Terocin.

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. Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments." 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 Drugs.com, Terocin is a topical analgesic containing capsaicin / lidocaine / menthol / methyl salicylate. The clinical documentation submitted for review failed to provide a rationale for both a topical patch and a topical cream formulation for Terocin. 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. There was a lack of documentation indicating the injured worker had not responded or was intolerant to other treatments. The request as submitted failed to indicate the frequency and body part to be treated. Given the above, the request for Terocin 240 mL cream is not medically necessary.

Gabacyclotram 180 cream: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Topical Analgesics, Gabapentin, Tramadol Page(s): 41, 111, 113, 82. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence:FDA.gov.

Decision rationale: The California Medical Treatment Utilization Schedule guidelines indicate that 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" - Gabapentin is not recommended. There is no peer-reviewed literature to support use. Other anti-epilepsy drugs: There is no evidence for use of any other anti-epilepsy drug as a topical product "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. 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 per CA Medical Treatment Utilization Schedule guidelines. 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. The clinical documentation submitted for review failed to provide documentation that the injured worker had trialed and failed antidepressants and anticonvulsants. There was a lack of documentation of exceptional factors, as multiple components are not recommended. As such, this medication is not recommended. There was a lack of documentation of objective functional benefit, an objective decrease in pain, and documentation the injured worker was being monitored for aberrant drug behavior and side effects. The request as submitted failed to indicate the body part and the frequency to be treated. Given the above, the request for gabacyclotram 180 cream is not medically necessary.

Somicin, QTY: 30: 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 Official Disability Guidelines (ODG) Pain Chapter, Insomnia Treatment and Other Medical Treatment Guidelines Other Medical Treatment Guideline or Medical Evidence: http://sales.advancedrxmgt.com/sales-content/uploads/2012/04/Somnicin-Patient-Info-Sheet.pdf.

Decision rationale: The Official Disability Guidelines indicates that non-pharmacologic treatment includes stimulus control, progressive muscle relaxation, and paradoxical intention and is a first line treatment for insomnia. Per advancedrxmgmt.com, the ingredients include Melatonin, 5-HTP, L-tryptophan, compound B-6 and Magnesium. Additionally, the Official Disability Guidelines, melatonin is recommended in the treatment of sleep disorders. A thorough search of the California MTUS, Official Disability Guidelines, and the National Guideline Clearinghouse failed to reveal guidelines or scientific evidence to L-tryptophan, pyridoxine, or magnesium in the management of insomnia. There was a lack of documentation indicating the injured worker had difficulty with sleep. There was a lack of documentation of exceptional factors. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Somnicin, quantity 30, is not medically necessary.

Genicin, QTY: 90: 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 Glucosamine Sulfate Page(s): 50.

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines recommend Glucosamine Sulfate for patients with moderate arthritis pain especially, knee osteoarthritis and that only one medication should be given at a time. The clinical documentation submitted for review failed to indicate the injured worker had moderate arthritis pain. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Genicin, quantity 90, is not medically necessary.