

Case Number:	CM15-0145478		
Date Assigned:	08/10/2015	Date of Injury:	07/01/2014
Decision Date:	09/23/2015	UR Denial Date:	06/24/2015
Priority:	Standard	Application Received:	07/27/2015

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: New York

Certification(s)/Specialty: Anesthesiology

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 68-year-old female who sustained an industrial injury on 07-01-2014. Current diagnoses include left shoulder rotator cuff tear. Previous treatments included medications, chiropractic, physical therapy, and home exercise program. Previous diagnostic studies included an MRI of the left shoulder dated 03-26-2015, and cardio-respiratory diagnostic testing on 03-16-2015. Initial injuries occurred to the left shoulder and upper arm when the worker was opening an overhead door. Report dated 05-14-2015 noted that the injured worker presented with complaints that included left shoulder pain. Pain level was 5 out of 10 on a visual analog scale (VAS). Currently the injured worker is working and performing full duty. Physical examination was positive for left shoulder decreased range of motion, tenderness to palpation along the biceps tendon, tenderness along the trapezius muscle bilaterally with palpable spasms, and supraspinatus isolation test is positive. The treatment plan included requests for compound medications, which included Terocin, Flurb (Nap) cream-LA, Gabaclyoctram, Genicin capsules, and Somnicin, dispensed medical foods, request for an orthopedic evaluation, continue home exercises, and follow up in 4-6 weeks. Disputed treatments include Terocin 240 ml (Capsaicin 0.025%-Methyl Salicylate 25%-Menthol 10%-Lidocaine 2.5%) Flurb (Nap) cream-LA 180gms (Flurbiprofen 20%-Lidocaine 5%-Amitriptyline 4%), Gabaclyoctram 190 mgs (Gabapentin 10%-Cyclobenzaprine 6%-Tramadol 10%), and Somnicin capsules (Melatonin 2mg, 5HTP 50mg, L tryptophan 100mg, Pyridoxine 10mg, Magnasium 50mg) #30.

IMR ISSUES, DECISIONS AND RATIONALES

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

Terocin 240 ml (Capsaicin 0.025%-Methyl Salicylate 25%-Menthol 10%-Lidocaine 2.5%):

Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin, Lidocaine, Topical Analgesics Page(s): 111-113.

Decision rationale: There is no documentation provided necessitating the use of the requested topical medication, Terocin. According to the California MTUS Guidelines, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate.

Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, local anesthetics or antidepressants. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case there is no documentation provided necessitating Terocin. This medication contains methyl salicylate, capsaicin, menthol, and lidocaine. MTUS states that capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. There is no documentation of intolerance to other previous medications.

Medical necessity for the requested topical medication has not been established. The requested treatment is not medically necessary.

Gabaclyctram 190 mgs (Gabapentin 10%-Cyclobenzaprine 6%-Tramadol 10%): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113.

Decision rationale: According to the California MTUS Guidelines, "Topical Analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control (for example, including NSAIDs, opioids, local anesthetics or antidepressants). Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, Gabapentin, Cyclobenzaprine and Tramadol are not FDA approved for a topical application. There is no peer-reviewed literature to support use. Medical necessity for the requested topical analgesic has not been established. The treating physician's request did not include the site of application. As such, the prescription is not sufficient and not medically necessary. Therefore, the request for Gabaclyctram 190 mgs (Gabapentin 10%-Cyclobenzaprine 6%-Tramadol 10%) is not medically necessary.

Somnicin capsules (Melatonin 2mg, 5HTP 50mg, L tryptophan 100mg, Pyridoxine 10mg, Magnesium 50mg) #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain chapter - Somnicin.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Somnicin.

Decision rationale: According to the ODG, melatonin is recommended for insomnia treatment. Melatonin also has an analgesic effect in patients with chronic pain. Somnicin contains melatonin, 5-HTP, L-tyrptopan, Vitamin B6 and magnesium. The medical records submitted did not indicate that the injured worker has sleep difficulty. Medical necessity for the requested item has not been established. The requested medication is not medically necessary.

Flurb (Nap) cream-LA 180gms (Flurbiprofen 20%-Lidocaine 5%-Amitriptyline 4%): 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 Page(s): 111-113.

Decision rationale: According to the California MTUS Guidelines, "Topical Analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control (for example, including NSAIDs, opioids, local anesthetics or antidepressants). Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Flurbiprofen, used as a topical NSAID, has been shown in a meta-analysis to be superior to placebo during the first two weeks of treatment for osteoarthritis but either, not afterward, or with diminishing effect over another two-week period. There are no clinical studies to support the safety or effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic), and topical Lidocaine is 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). They also note that, with an exception of a dermal patch, no commercially approved topical formulations of Lidocaine (whether cream, lotions, or gels) are indicated for neuropathic pain." There is a lack of documentation that the injured worker is intolerant of other treatments. In addition, since the guidelines do not recommend several of the ingredients, there is no medical necessity for this compound. The treating physician's request did not include the site of application. As such, the prescription is not sufficient and not medically necessary. Medical necessity for the requested topical agent is not established. The request for Flurb (Nap) cream-LA 180gms (Flurbiprofen 20%-Lidocaine 5%-Amitriptyline 4%) is not medically necessary.