

Case Number:	CM14-0174343		
Date Assigned:	11/04/2014	Date of Injury:	02/14/2011
Decision Date:	01/16/2015	UR Denial Date:	10/13/2014
Priority:	Standard	Application Received:	10/20/2014

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. The expert reviewer is Board Certified in Physical Medicine & Rehabilitation, and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 patient is a 37 year old female with date of injury 2/14/11 from repetitive movements. The treating physician report dated 8/4/14 indicates that the patient presents with pain affecting lower back, neck, bilateral wrist. Lower back pain is noted as intermittent which radiates to the lower extremities. Patient's neck pain is secondary to her stress. Patient's bilateral wrist pain is accompanied by a tingling sensation and numbness. The physical examination findings reveal tenderness over the paralumbar muscles and spinous processes. ROM reveals flexion of 60 degrees, extension of 20 degrees, right and left lateral bending of 20 degrees. Straight leg raise was accomplished at 60 degrees bilaterally. In the bilateral wrists there is tenderness to palpation bilaterally with full ROM. Prior treatment history includes prescribed medications, home IF 4 unit, chiropractic treatments and aquatic physical therapy. MRI findings reveal mild disc desiccation and broad-based disc protrusion at L4-L5 and L5-S1, as well as straitening of the lumbar lordotic curvature. A 60.2 mm cyst like structure was found in the left adnexal region. The current diagnoses are: Chronic low back pain with associated radiculitis; History of chronic repetitive disorder, bilateral wrists/hands and Carpal tunnel syndrome, bilateral. The utilization review report dated 10/13/14 denied the request for Flurbi (NAP) cream-LA180gms: Flurbiprofen 20%, Lidocaine 5%, Amitriptyline 4%:, Gabacyclotram 180gms: Gabapentin 10%, Cyclobenzaprine 6%, Tramadol 10%:, Terocin 240ml: Capsaicin 0.025%, Methyl Salicylate 25%, Menthol 10%, Lidocaine 2.5%:, Menthoderm Gel 120gm, Xolido 2% 118ml cream, Theramine #90, Trepadone #120, Genicin (Glucosamine Sodium) 500mg #90, Somnicin #30: Melatonin 2mg, 5HTP 50mg, L Tryptophan 100mg, Pyridoxine 10mg, Magnesium 50mg based on the requests not satisfying MTUS guidelines.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbi (NAP) cream-LA180gms: Flurbiprofen 20%, Lidocain 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 Page(s): 111-113.

Decision rationale: The patient presents with chronic low back, neck and wrist pain over 3 years post injury. The current request is for Flurbi (NAP) cream-LA180gms: Flurbiprofen 20%, Lidocaine 5%, and Amitriptyline 4%. Regarding compounded topical analgesics MTUS states "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." "These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder." "Lidocaine Indication: Neuropathic pain 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)." "Non-neuropathic pain: Not recommended. There is only one trial that tested 4% Lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo." "Topical Lidocaine in the formulation of a dermal patch has been designated for orphan status by the FDA for neuropathic pain. No other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain." There is no evidence of a previous trial of first line therapy that was provided in order to warrant the use of Lidocaine. Additionally Lidocaine is approved for use only in the form of a patch. In this case the use of Lidocaine is not recommended therefore the request for the entire topical compound does not satisfy MTUS guidelines. Therefore, this request is not medically necessary.

Gabaclosetram 180gms: Gabapentin 10%, Cyclobenzaprine 6%, Tramadol 10%: Upheld

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

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

Decision rationale: The patient presents with chronic low back, neck and wrist pain over 3 years post injury. The current request is for Gabaclosetram 180gms: Gabapentin 10%, Cyclobenzaprine 6%, and Tramadol 10%. Regarding compounded topical analgesics MTUS states "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." In this case Gabapentin is not recommended in the MTUS guidelines and therefore the entire topical compound is not recommended. Therefore, this request is not medically necessary.

Terocin 240ml: Capsaicin 0.025%, Methyl Salicylate 25%, Menthol 10%, Lidocaine 2.5%: Upheld

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

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

Decision rationale: The patient presents with chronic low back, neck and wrist pain over 3 years post injury. The current request is for Terocin 240ml: Capsaicin 0.025%, Methyl Salicylate 25%, Menthol 10%, and Lidocaine 2.5%. Regarding compounded topical analgesics MTUS states "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." The MTUS guidelines state for Lidocaine, "No other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain." In this case the use of Lidocaine is not recommended therefore the request for the entire topical compound does not satisfy MTUS guidelines. Therefore, this request is not medically necessary.

Menthoderm Gel 120gm: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.drugs.com/cdi/menthoder-cream.html

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

Decision rationale: The patient presents with chronic low back, neck and wrist pain over 3 years post injury. The current request is for Menthoder Gel 120gm. Menthoder is a topical cream containing methyl salicylate and menthol. The MTUS Guidelines state that topical NSAIDS are indicated for peripheral joint arthritis and tendinitis. In this case the treating physician has indicated that the patient has chronic pain affecting the wrists and hands. This topical analgesic is supported by MTUS and the request is medically necessary.

Xolido 2% 118ml cream: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=f2b463d7-3fcf-4b2c-8ba2-8e51e3290de2>

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

Decision rationale: The patient presents with chronic low back, neck and wrist pain over 3 years post injury. The current request is for Xolido 2% 118ml cream. Xolido is a topical cream containing Lidocaine. . The MTUS guidelines state that Lidocaine can be used in patch form and goes on to state, "No other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain." In this case the use of Lidocaine is not recommended therefore the request for the entire topical compound does not satisfy MTUS guidelines. Therefore, this request is not medically necessary.

Theramine #90: 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

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

Decision rationale: The patient presents with chronic low back, neck and wrist pain over 3 years post injury. The current request is for Theramine #90. According to the ODG medical food is "Not recommended for chronic pain. Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. FDA defines a medical food as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain" In this case the current request does not satisfy the ODG. Therefore, this request is not medically necessary.

Trepadone #120: 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

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

Decision rationale: The patient presents with chronic low back, neck and wrist pain over 3 years post injury. The current request is for Trepadone #120. According to the ODG medical food is "Not recommended for chronic pain. Medical foods are not recommended for treatment

of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. FDA defines a medical food as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain" In this case the current request does not satisfy the ODG. Therefore, this request is not medically necessary.

Genicin (Glucosamine Sodium) 500mg #90: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 50.

Decision rationale: The patient presents with chronic low back, neck and wrist pain over 3 years post injury. The current request is for Genicin (Glucosamine Sodium) 500mg #90. According to the MTUS guidelines Glucosamine is "Recommended as an option (glucosamine sulfate only) given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis." In this case the patient has been diagnosed with chronic back, neck and wrist pain that is arthritic in nature. The MTUS guidelines support the usage of Glucosamine. Therefore, this request is medically necessary.

Somnicin #30: Melatonin 2mg, 5HTP 50mg, L Tryptophan 100mg, Pyridoxine 10mg, Magnesium 50mg: 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

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

Decision rationale: The patient presents with chronic low back, neck and wrist pain over 3 years post injury. The current request is for Somnicin #30: Melatonin 2mg, 5HTP 50mg, L Tryptophan 100mg, Pyridoxine 10mg, and Magnesium 50mg. According to the ODG, "FDA defines a medical food as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain." Somnicin is noted as medical food in the medical food class. Somatic Functioning Consultation was conducted on

patient on 03/17/14. It was noted that the overall disability in regards to her sleep condition would be 2% due to initiating insomnia. The treating physician did note that these symptoms were temporary and suggested that symptoms could be relieved with a change in habits. In this case even though there is discussion of the patients problematic sleep patterns there is no evidence provided by the treating physician on the success/failure of prior non-pharmacological treatments. Additionally there is no discussion of whether the treating physician requested this medication for the patient's pain or insomnia. Therefore, this request is not medically necessary.