

Case Number:	CM13-0057858		
Date Assigned:	12/30/2013	Date of Injury:	02/09/2012
Decision Date:	04/30/2014	UR Denial Date:	10/08/2013
Priority:	Standard	Application Received:	10/16/2013

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, has a subspecialty in Neuromuscular Medicine, and is licensed to practice in Maryland. 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 51 year-old female who had a work related injury on 2/9/12 to her to the right shoulder, wrist and neck. Her diagnoses include 1) Right shoulder internal derangement. 2) Right hand CTS. 3) Cervical spine multiple disc protrusion & stenosis. 4) Anxiety and depression. There are requests for Terocin. Flurbiprofen, Somnicin. Laxacin, Gabacyclotram cream. There is a 9/24/13 primary treating physician report that states that the patient complains of cervical pain radiating to left shoulder. The pain is a 5/10. The patient has insomnia that persists. Patient complains of constant pin and needles in the bilateral shoulders, Pain in low back radiates down to right leg. The physical exam states: "See dictated report" (dictated report not included). The plan on this date was urine toxicology, genetic testing. Topical compounds. Terocin 240ml, Somacin #30. Flurbiprofen 180 gm. Laxacin # 100. Gabacyclotram 180 gm. Follow up with hand surgeon. Also a shoulder surgery consultation. A 12/17/13 primary treating physician progress report states that topical compounds and medication help pain.H-wave is effective. Right shoulder pins and needles 7/10, neck stiffness, wrist brace approved. IF unit helps. The patient cannot hold grandson. Her personal hygiene is an issue. She has uncontrollable right upper extremity spasms. On physical exam she has continued severe tenderness right shoulder with decreased range of motion. The right wrist has severe tenderness, painful and decreased range of motion. The plan includes continuing Terocin. Flurbiprofen, Somnicin. Laxacin, Gabacyclotram cream.

IMR ISSUES, DECISIONS AND RATIONALES

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

TEROCIN, 240ML: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines LIDODERM Page(s): 105; 111-113; 56-57.

Decision rationale: Terocin 240 ml is not medically necessary per MTUS guidelines. According to the Chronic Pain Treatment Guidelines MTUS, there is little use to support the use of many of these agents. (Topical analgesics) Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The active ingredient in Terocin Lotion are :Methyl Salicylate 25%,Capsaicin 0.025%, Menthol 10% Lidocaine 2.50% .Terocin contains Lidocaine which per MTUS guidelines : "Topical Lidocaine 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). This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia." Patient has no documentation that she meets the criteria for topical lidocaine and therefore this is not medically necessary. Capsaicin is contained, Final Determination Letter for IMR Case Number CM13-0057858 4, within Terocin and per MTUS: Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. There is no documentation that patient is intolerant to other oral medications or treatments. Salicylate topical is recommended by the MTUS and Terocin contains methyl Salicylate .Menthol- The MTUS guidelines do not specifically discuss menthol. There is mention of Ben-Gay which has menthol in it and is medically used per MTUS for chronic pain. The patient does not meet the criteria for either Capsaicin or lidocaine in this case and therefore the entire compounded product is not medically necessary. The request therefore for Terocin 240 ml is not medically necessary.

FLURBIPROFEN, 180GM: Upheld

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

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

Decision rationale: Flurbiprofen 180 gm is not medically necessary per MTUS guidelines. Per guidelines, "Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety." Additionally, guidelines state, "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. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder." There are no clinical indications for topical NSAIDs in this patient from documentation submitted. Furthermore the request for Flurbiprofen is not clear on what body

part patient is applying this medication to. The request for Flurbiprofen 180 gm is not medically necessary.

30 SOMNICIN: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG), PAIN-INSOMNIA TREATMENT AND MEDICAL FOODS, AND [HTTP://BEFOREITSNEWS.COM/HEALTH/2013/01/SOMNICIN-A NEW-DRUG FOR INSOMNIA-AND-DEPRESSION-TO-BE-RELEASED-REPORTERS REVEALED-2465790.HTML](http://beforeitsnews.com/health/2013/01/somnicin-a-new-drug-for-insomnia-and-depression-to-be-released-reporters-revealed-2465790.html)

Decision rationale: Somnicin 30 is not medically necessary per ODG guidelines. The MTUS does not specifically discuss Somnicin or insomnia. The ODG states that pharmacological agents should only be used for insomnia after careful evaluation of potential causes of sleep disturbance. Somnicin is considered a medical food. The ODG states that a medical food is "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, Final Determination Letter for IMR Case Number CM13-0057858 5, nutritional requirements, based on recognized scientific principles, are established by medical evaluation." Per the manufacturer, Somnicin is a hypnotic medication consisting of Melatonin, 5-HTP, Ltryptophan, Vitamin B6, and Magnesium. The documentation does not indicate that there has been a discussion of the etiology of patient's sleep disturbance. Also the documentation does not indicate that patient has a unique requirement for this nutritional supplement. Therefore the request for Somnicin 30 is not medically necessary.

100 LAXACIN: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation NAPHARM.COM

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines INITIATING THERAPY, LAXACIN Page(s): 77. Decision based on Non-MTUS Citation [HTTP://DAILYMED.NLM.NIH.GOV/](http://dailymed.nlm.nih.gov/)

Decision rationale: 100 Laxacin containing a laxative and stool softener consisting of Docusate sodium and Sennosides is not medically necessary. The MTUS does support the use of medications for constipation prophylaxis when patients are using chronic opiates. Although the documentation indicates that the patient is using Oxycodone there are no specific reasons why patient requires this particular compounded formula of 2 medications. Laxacin is a combination laxative and stool softener consisting of Docusate sodium, a stool softener, and Sennosides. There has been no documentation of constipation for this patient or documentation why the

patient needs this particular combination of ingredients over standard first line therapy. The request for 100 Laxacin is not medically necessary.

GABACYCLOTRAM, 180GM: Upheld

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

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

Decision rationale: Gabacyclotram, 180gm is not medically necessary per the MTUS guidelines. The requested cream contains gabapentin, Cyclobenzaprine and Tramadol. The MTUS Chronic Pain Medical Treatment Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. The guidelines states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The documentation does not reveal any intolerance to oral medications. The MTUS does not recommend topical gabapentin or Cyclobenzaprine therefore the request for Gabacyclotram 180gm is not medically necessary.