

<b>Case Number:</b>	CM13-0071484		
<b>Date Assigned:</b>	12/11/2014	<b>Date of Injury:</b>	05/01/2012
<b>Decision Date:</b>	01/15/2015	<b>UR Denial Date:</b>	12/17/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/27/2013

### 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 and 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 34 year old male with a work injury due to a fall dated 5/1/12. The diagnoses include right shoulder, left knee, left elbow I&D; lumbosacral radiculopathy, right ankle I&D; anxiety and depression. The patient is status post left dorsal wrist ganglion cyst removed; left triangular fibrocartilage complex tear repair; left scapulohumeral ligament repair on 10/2/13. Under consideration are requests for Terocin; Flurbi; Somnicin; Laxicin; Gabaclyoctram. The 12/3/13 primary treating physician handwritten, somewhat illegible progress report states that the patient complains of 3/10 pain in the left elbow; 5/10 left shoulder stabbing pain; neck pain radiating from bilateral shoulders 4/10 that affects hearing; right shoulder pain 8/10; right wrist stiff with pins and needles; right finger (?); right elbow stiff/cramping 4/10; left lower extremity cramping 4/10. On exam the left wrist cast was removed. Wounds are clear. Range of motion is stiff. Supination is 30% and pronation 40% and Dorsiflexion 15 degrees and plantar flexion is 10 degrees. There are decreased motor and sensory findings. The right shoulder is severe painful range of motion. The treatment plan includes genetic testing for narcotics risk, urine toxicology; multiple topical medications to reduce pain and oral medications; multiple referrals for consultations; psychologist; radiologist; EMG/NCS; PT for the wrist. The patient is to remain off of work.

### 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 Topical Analgesics Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate topicals; Topical analgesics; Lidoderm (lidocaine patch) Page(s): 105; 111-113; 56-.

**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 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 topicals are 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.

**Flurbi 180 grams:** Upheld

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

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

**Decision rationale:** Flurbi 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." The guidelines state that topical NSAIDs (such as Flurbiprofen) are indicated for osteoarthritis and tendinitis, in particular that of the knee and elbow or other joints that are amenable to topical treatment for short-term use (4-12 weeks). The documentation indicates that the patient has been using Flurbiprofen longer than the recommended time period without significant evidence of functional improvement. 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.

**Somnicin #30:** Upheld

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

**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 American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) Updated ACOEM Guidelines, Pain section; Complementary, alternative treatments, or dietary supplements, etc., page 135

**Decision rationale:** Somnicin 30 is not medically necessary per the ODG and the MTUS guidelines. The ACOEM and the MTUS guidelines state that complementary and alternative treatments, or dietary supplements, etc., are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. 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 internally 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." 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.

**Laxacin #100:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Initiating Therapy Page(s): 77. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: (Laxacin) <http://dailymed.nlm.nih.gov/>

**Decision rationale:** Laxacin #100 is not medically necessary per the MTUS Guidelines. Laxacin contains a laxative and stool softener consisting of Ducosate 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 hydrocodone per an 8/29/13 urine toxicology screen 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 Ducosate sodium, a stool softener, and

Sennosides. There has been no documentation of why the patient needs this particular combination of ingredients over standard first line therapy. The request for 100 Laxacin is not medically necessary.

**Gabacyclotram 180 grams:** Upheld

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