

<b>Case Number:</b>	CM13-0041364		
<b>Date Assigned:</b>	12/20/2013	<b>Date of Injury:</b>	07/16/2010
<b>Decision Date:</b>	03/05/2014	<b>UR Denial Date:</b>	10/07/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/14/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Pain Management, has a subspecialty in Disability Evaluation 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 physician 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 53-year-old male who sustained a continuous injury which was reported on 7/16/2010 while working for [REDACTED]. The patient states that he developed knee pain secondary to getting into and out of his delivery truck, as well as running up and down the stairs at the warehouse when the elevator was broken. The patient complains of acute exacerbation of pain in his back mostly on the right radiating into the right lower extremity radicular in nature, as well as the right knee pain. The patient also continues to complain of neck pain which radiates into both upper extremities. He was diagnosed with cervical cord myelopathy with central cord syndrome; He underwent an anterior cervical fusion at C2-3, C3-4, C4-5, C5-6 and C6-7 on August 27, 2011. The patient had a bone scan and CT scan of the cervical spine on March 5, 2013; it was notes that the patient had a pseudarthrosis at C3-4 and C6-7. Due to ongoing and debilitating pain with significant functional limitations of the upper and lower extremities, the patient remains a high risk for fall. The patient is unable to use his manual wheelchair because of difficulty manually propelling the wheelchair with his lack of strength. The patient has had several falls while ambulating in his home and he states that he is mostly housebound, as he is fully aware that he is a high fall risk. Currently the patient complains of stiffness all over his body, he describes numbness and tingling of his limbs, weakness all over with no swelling. In the most recent progress report dated 09/24/13 indicates that the claimant was seen by QME. The patient has dry scabs on the body. The claimant's left knee is giving out. The claimant experiences numbness and tingling in the cervical area. The claimant continues to have severe pain, decreased range of motion, decreased muscle strength, and sensation. There are dermatological lesions over the arms. The provider recommends urine toxicology, genetic testing for narcotics, topical compounds to reduce pain, and oral medications. The provider also

recommends consultation with neurosurgeon and pain management. The claimant remains off work.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **Terocin 240 ml: 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).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Section Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Low Back Chapter

**Decision rationale:** Terocin is a Topical Pain Relief Lotion containing Methyl Salicylate 25%, Capsaicin 0.025%, Menthol 10%, and Lidocaine 2.50%. According to MTUS guidelines, the use of topical analgesics is largely experimental with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. In this patient there is no documentation that the recommended first line medications have been tried and failed. Also, the guidelines do not recommend compound medications including lidocaine (in creams, lotion or gels), for topical applications and any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. While guidelines would support a capsaicin formulation, the above compounded topical medication is not recommended. Therefore the request for Terocin 240 ml is not medically necessary.

#### **Flurbi 180 gm: 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).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Section Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Low Back Chapter.

**Decision rationale:** Flurbi 180gm does not satisfy the California MTUS Guidelines or the Official Disability Guidelines (ODG). It has not been established that there has been inadequate analgesia, intolerance or side effects from the more accepted first-line medications prior to consideration of compound topical formulations. Also the guideline states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. It has not been established that there has been inadequate analgesia, intolerance or side effects from the more accepted first-line medications prior to consideration of compound topical formulations. There is no indication that oral medications are insufficient to manage pain. With all these factors to consider, as well as lack of peer-reviewed literature to support use, the medical necessity of Flurbi 180 gm is not established. In order for this medication to be

considered for neuropathic pain, the provider has to document failed trials of anticonvulsants and antidepressants. Therefore the request for Flurbi 180gm is not medically necessary.

**Somnicin #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)

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

**Decision rationale:** HTP (5-hydroxytryptopan) 50 mg, L-tryptophan 100 mg, Vitamin B6 (pyridoxine) 10 mg, Magnesium 50 mg. According to USFDA website, The term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) 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 nutritional requirements, based on recognized scientific principles, are established by medical evaluation..Medical foods are not drugs and, therefore, are not subject to any regulatory requirements that specifically apply to drugs. For example, medical foods do not have to undergo premarket review or approval. According to up-To-Date reference Melatonin -- Melatonin is a hormone that is normally produced by a gland in the brain. Melatonin does not appear to be helpful in most people who have insomnia, except in people with delayed sleep phase syndrome. There is no documentation that this patient has delayed sleep phase syndrome. In addition the dosage of L-tryptophan and 5-Hydroxytryptopan contained in Somnicin is far below the recommended dosage for use in treating insomnia (1-4 gm). Therefore Somnicin capsules 30 for 30 days supply is not medical necessary.

**Laxacin #100:** 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)

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation website WebMD

**Decision rationale:** Regarding Laxacin #100, according to WebMD this product is used to treat constipation. It contains 2 medications: sennosides and docusate. Sennosides are known as stimulant laxatives. They work by keeping water in the intestines, which helps to cause movement of the intestines. Docusate is known as a stool softener. It helps increase the amount of water in the stool, making it softer and easier to pass. notes In this case, without evidence of constipation and with non-certification of Butrans patch, the medical necessity for Laxacin #100 is not established.

**Gabaclotram 180 gm:** 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).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Section Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Chronic Pain Chapter

**Decision rationale:** The guideline does not support the use of Tramadol, Cyclobenzaprine and Gabapentin as topical agents. The guideline further stated that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended". Therefore the request for 1 prescription Gabacyclotram 180gm is not medically necessary.

**Butrans patch:** 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)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Buprenorphine Section Page(s): 26. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Chronic Pain Chapter

**Decision rationale:** Regarding Butrans patch, CA MTUS notes that Buprenorphine is recommended for treatment of opiate addiction. Also recommended as an option for chronic pain, especially after detoxification in patients who have a history of opiate addiction. In this case, the claimant presents with severe pain over the cervical spine. However, there is no documentation of opiate addiction, or the claimant undergoing detoxification from opioids. Treatment plan is not indicated, such as end-plan and goals with Butrans patch use. Without such, the medical necessity of Butrans patch is not established.