MAXIMUS Federal Services

| Case Number: | CM14-0007532 | | |
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| Date Assigned: | 02/10/2014 | Date of Injury: | 05/27/2013 |
| Decision Date: | 07/11/2014 | UR Denial Date: | 01/11/2014 |
| Priority: | Standard | Application Received: | 01/21/2014 |

## 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 Occupational Medicine 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:

Patient is a 33-year-old female who has submitted a claim for lumbar disc herniation with radiculopathy, and left shoulder internal derangement associated with an industrial injury date of May 27, 2013. Medical records from 2013 - 2014 were reviewed. Patient complained of persistent low back pain radiating to the left lower extremity, associated with numbness, graded 10/10 in severity. This resulted in difficulty walking. Patient likewise complained of left shoulder pain with numbness and tingling sensation at the left upper extremity. Physical examination of the lumbar spine revealed painful and restricted range of motion. Weakness and diminished sensation were noted at the left lower extremity. Range of motion of the left shoulder was restricted. Neer test and Hawkins test were positive. Treatment to date has included Cyclobenzaprine, Hydrocodone, topiramate, naproxen, and aspirin. Utilization review from January 11, 2014 denied the retrospective requests for Terocin patch, Flurbi (nap) cream-la, gaba/cyclo/tram, and Somnicin because compounded medications have insufficient efficacy and safety profile.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**RETROSPECTIVE TEROCIN PATCH, DURATION AND FREQUENCY UNKNOWN FOR NECK, LEFT SHOULDER, BACK FOR FOR DATES OF SERVICE FROM 08/23/2013 TO 08/24/2013:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL SALICYLATE Page(s): 105.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidocaine patch Page(s): 56-57. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Section, Topical Salicylate.

**Decision rationale:** Terocin patch contains both lidocaine and menthol. Pages 56 to 57 of CA MTUS Chronic Pain Medical Treatment Guidelines state that 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). Regarding the Menthol component, CA MTUS does not cite specific provisions, but the ODG Pain Chapter states that the FDA has issued an alert in 2012 indicating that topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns. In this case, patient's presentation is consistent with neuropathic pain. She was prescribed topiramate, however, symptoms persisted. This prompted adding Terocin patch in her current treatment regimen. The medical necessity was established. Therefore, the retrospective request for terocin patch, duration and frequency unknown for neck, left shoulder, back for for dates of service from 08/23/2013 to 08/24/2013 was medically necessary.

**RETROSPECTIVE FLURBI (NAP) CREAM-LA DURATION AND FREQUENCY UNKNOWN FOR NECK, LEFT SHOULDER, BACK FOR DATES OF SERVICE FROM 08/23/2013 TO 08/24/2013:** 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:** As noted on pages 111-113 in the CA MTUS Chronic Pain Medical Treatment Guidelines, there is little to no research as for the use of Flurbiprofen in compounded products. Topical formulations of lidocaine (whether creams, lotions or gels) are not indicated for neuropathic or non-neuropathic pain complaints. Amitriptyline is a tricyclic antidepressant considered first-line agents, but there is no discussion regarding topical application of this drug. In this case, topical medications were prescribed to limit the use of oral medications. However, there is no discussion concerning the need for multiple topical medications. In addition, certain components of this compound are not recommended for topical use. The guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. There is likewise no evidence of intolerance to oral medications. Therefore, the retrospective request for flurbi (nap) cream-la duration and frequency unknown for neck, left shoulder, back for dates of service from 08/23/2013 to 08/24/2013 was not medically necessary.

**RETROSPECTIVE GABA/CYCLO/TRAM DURATION AND FREQUENCY UNKNOWN FOR NECK, LEFT SHOULDER, BACK FOR FOR DATES OF SERVICE FROM 08/23/2013 TO 08/24/2013:** 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 CA MTUS Chronic Pain Medical Treatment Guidelines pages 111-113, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Gabapentin is not recommended for use as a topical analgesic. Likewise, Cyclobenzaprine has no evidence for use as a topical product. Tramadol is indicated for moderate to severe pain. In this case, topical medications were prescribed to limit the use of oral medications. However, there is no discussion concerning the need for multiple topical medications. In addition, certain components of this compound are not recommended for topical use. The guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. There is likewise no evidence of intolerance to oral medications. Therefore, the retrospective gaba/cyclo/tram duration and frequency unknown for neck, left shoulder, back for for dates of service from 08/23/2013 to 08/24/2013 was not medically necessary.

**RETROSPECTIVE SOMNICIN DURATION AND FREQUENCY UNKNOWN FOR NECK, LEFT SHOULDER, BACK FOR DATES OF SERVICE FROM 08/23/2013 TO 08/24/2013:** 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) Pain Section, Medical Foods.

**Decision rationale:** The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, the Official Disability Guidelines (ODG), Pain Section was used instead. Somnicin #30 contains Melatonin, 5-hydroxytrptophan, L-tryptophan, Magnesium, and vitamin B-6. ODG states that medical foods are formulated 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. 5-hydroxytryptophan has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity, depression, and sleep disorders. In this case, the submitted records failed to include a rationale or laboratory values indicating nutritional deficiency. There is no discussion as to why this medication is being prescribed. A search in the FDA database did not provide any results for Somnicin. The FDA states that specific requirements for the safety or appropriate use of medical foods have not yet been established. Therefore, the request for retrospective somnicin duration and frequency unknown for neck, left shoulder, back for dates of service from 08/23/2013 to 08/24/2013 is not medically necessary.