

Case Number:	CM14-0013265		
Date Assigned:	02/26/2014	Date of Injury:	07/18/2013
Decision Date:	07/21/2014	UR Denial Date:	01/07/2014
Priority:	Standard	Application Received:	02/03/2014

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 male who has submitted a claim for headache, neck sprain / strain, brachial neuritis / radiculitis, lumbar sprain / strain, bilateral shoulder internal derangement, right shoulder full rotator cuff tear, and right ankle sprain / strain associated with an industrial injury date of 07/18/2013. Medical records from 2013 to 2014 were reviewed. Patient complained of constant neck pain radiating to the right upper extremity, graded 3 - 4/10 in severity. Patient likewise experienced constant low back pain, constant bilateral shoulder pain, left knee pain and right ankle / foot pain. Physical examination revealed tenderness and restricted range of motion of both cervical and lumbar spine. Motor strength, reflexes, and sensory exam were unremarkable. Treatment to date has included physical therapy, acupuncture, Vicodin, and topical medications. Utilization review from 01/07/2014 denied the requests for Somnicin #30/melatonin 2mg-5htp 50mg-l tryptophan 100mg-pyridoxine 10mg-magnesium 50mg because of its limited published efficacy; Terocin 240ml: Patient is a 33-year-old male who has submitted a claim for headache, neck sprain / strain, brachial neuritis / radiculitis, lumbar sprain / strain, bilateral shoulder internal derangement, right shoulder full rotator cuff tear, and right ankle sprain / strain associated with an industrial injury date of 07/18/2013. Medical records from 2013 to 2014 were reviewed. Patient complained of constant neck pain radiating to the right upper extremity, graded 3 - 4/10 in severity. Patient likewise experienced constant low back pain, constant bilateral shoulder pain, left knee pain and right ankle / foot pain. Physical examination revealed tenderness and restricted range of motion of both cervical and lumbar spine. Motor strength, reflexes, and sensory exam were unremarkable. Treatment to date has included physical therapy, acupuncture, Vicodin, and topical medications. Utilization review from 01/07/2014 denied the requests for Somnicin #30/melatonin 2mg-5htp 50mg-l tryptophan 100mg-pyridoxine 10mg-magnesium 50mg because of its limited published efficacy; Terocin 240ml: capcaicin

0.025%-methyl salicylate 25%-menthol 10%-lidocaine 2.5%: Flurbi (NAP) cream 180gm: flurbiprofen 20%-lidocaine 5%-amitriptyline 4%; and gabacyclotram 180gm: gabapentin 10%/cyclobenzaprine 6%/ tramadol 10% because topical compounded products are generally not recommended if it contains at least one drug class that is not recommended. capsaicin 0.025%-methyl salicylate 25%-menthol 10%-lidocaine 2.5%: Flurbi (NAP) cream 180gm: flurbiprofen 20%-lidocaine 5%-amitriptyline 4%; and gabecyclotram 180gm: gabapentin 10%/cyclobenzaprine 6%/ tramadol 10% because topical compounded products are generally not recommended if it contains at least one drug class that is not recommended.

IMR ISSUES, DECISIONS AND RATIONALES

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

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)- Medical food.

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 documented rationale for prescribing Somnicin is to treat insomnia and anxiety, while promoting muscle relaxation. Sleep Disordered Breathing Respiratory Study on 10/19/13 showed mild pathological sleep breathing disorder. However, there are no laboratory values indicating nutritional deficiency, which may necessitate Somnicin. A search in the FDA database did not provide any results. The FDA states that specific requirements for the safety or appropriate use of medical foods have not yet been established. Moreover, patient has been prescribed Somnicin since September 2013; however, recent progress reports failed to provide evidence of functional improvement attributed to its use. Therefore, the request for Somnicin #30/Melatonin 2mg-5htp 50mg-L Tryptophan 100mg-Pyridoxine 10mg-Magnesium 50mg 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 Capsaicin, topical.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin, page 28; Topical Analgesics Page(s): 28; 111-113.

Decision rationale: Terocin lotion contains: methyl salicylate 25%, capsaicin 0.025%, menthol 10%, and lidocaine 2.50%. Regarding the capsaicin component, the guideline states there is no current indication that an increase over a 0.025% formulation would provide any further efficacy. Guidelines state that capsaicin in a 0.0375% formulation is not recommended for topical applications. Regarding the Lidocaine component, CA MTUS Chronic Pain Medical Treatment Guidelines identify on page 112 that topical formulations of lidocaine (whether creams, lotions or gels) are not indicated for neuropathic or non-neuropathic pain complaints. According to the guideline, topical salicylate is significantly better than placebo in chronic pain. 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 (over the counter) pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns. In this case, patient has been on this topical product since September 2013. However, progress report from October 15, 2013 cited that patient was allergic to topical medications. Moreover, guidelines state that any compounded product that contains at least one drug that is not recommended is not recommended. Lidocaine is not recommended for topical use. There is likewise no discussion concerning the need for multiple topical analgesics in this case. Therefore, the request for Terocin 240ml: Capsaicin 0.025%-Methyl Salicylate 25%-Menthol 10%-Lidocaine 2.5% is not medically necessary.

FLURBI (NAP) CREAM 180GM: FLURBIPROFEN 20%-LIDOCAINE 5%-AMITRIPTYLINE 4%: Upheld

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

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, patient has been on this topical product since September 2013. However, progress report from October 15, 2013 cited that patient was allergic to topical medications. Moreover, guidelines state that any compounded product that contains at least one drug that is not recommended is not recommended. Lidocaine is not recommended for topical use. There is likewise no discussion concerning the need for multiple topical analgesics in this case. Therefore, the request for Compound Flurbi (Nap) Cream - LA 180gms: Flurbiprofen 20% - Lidocaine 5% - Amitriptyline 4% is not medically necessary.

GABACYCLOTRAM 180GM: GABAPENTIN 10%/CYCLOBENZAPRINE 6%/ TRAMADOL 10%.: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Compounded medications.

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, patient has been on this topical product since September 2013. However, progress report from October 15, 2013 cited that patient was allergic to topical medications. Moreover, this product contains cyclobenzaprine and gabapentin, which are not recommended for topical use. There is likewise no discussion concerning the need for multiple topical analgesics in this case. Therefore, the request for Compound Gabacyclotram 180mg Gabapentin 10% - Cyclobenzaprine 6% - Tramadol 10% is not medically necessary.