

Case Number:	CM14-0023467		
Date Assigned:	02/26/2014	Date of Injury:	06/20/2012
Decision Date:	08/15/2014	UR Denial Date:	02/14/2014
Priority:	Standard	Application Received:	02/24/2014

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 Anesthesiology, has a subspecialty in Pain Management, and is licensed to practice in Tennessee. 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 52-year-old who has submitted a claim for lumbar radiculopathy, lumbar spinal stenosis, lumbar spondylosis, lumbar disc protrusion, left elbow contusion, left knee status post partial anterior cruciate ligament tear and medial meniscal tear, and diabetes associated with an industrial injury date of June 20, 2012. Medical records from 2013 to 2014 were reviewed. Patient complained of pain at the lumbar spine, left elbow, and left knee, graded 4/10 in severity. Low back pain radiated to bilateral lower extremities. Physical examination of the lumbar spine showed hypertonicity, tenderness, and restricted range of motion. Straight leg raise test was positive bilaterally at 60 degrees with pain radiating down the posterior thigh. Left knee examination showed limited range of motion, tenderness, and a positive patellofemoral grind test. Treatment to date has included left knee ACL repair, lumbar epidural steroid injections, left knee cortisone injections, physical therapy, and medications. Utilization review from February 4, 2014 denied the request for Terocin pain patch, #20 because of lack of documentation concerning indication for its use; denied Genicin because there was no diagnosis of knee osteoarthritis, and denied the requests for Theramine, Gabadone, Sentra AM, and Sentra PM because of unclear documentation concerning the need to provide multiple medications for insomnia. The requests for Terocin 240mg (capsaicin 0.025%, menthyl salicyclate 25%, menthol 10%, lidocaine 2.5%), Flurbi (NAP) cream 180 gms (flurbiprofen 20%, lidocaine 5%, amitriptyline 4%), and Gabacyclotram 180 mgs (gabapentin 10%, cyclobenzaprine 6%, tramadol 10%) were denied because of limited published efficacy and safety for its use.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine, ninety count: 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 (Chronic) Section, Theramine.

Decision rationale: The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, Official Disability Guidelines, Pain section was used instead. ODG states that Theramine is a medical food that is a proprietary blend of GABA (gamma-aminobutyric acid) and choline bitartrate, L-arginine and L-serine that is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain and inflammatory pain. However, it remains not recommended by the guidelines. In this case, no progress report was made available citing Theramine prescription. There was no documented rationale for this request. The medical necessity cannot be established due to insufficient information. Therefore, the request for Theramine, ninety count is not medically necessary or appropriate.

Sentra AM, sixty count: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Non-MTUS website tmedpharma.com (www.tmedpharma.com/docs/monographs-10-09/Sentra_AM_Monograph_v_Final_10-15-2009.pdf).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Medical Food Section Other Medical Treatment Guideline or Medical Evidence http://www.ptlcentral.com/downloads/monographs/Sentra_AM_latest.pdf.

Decision rationale: The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, Official Disability Guidelines (ODG) Pain Chapter, Medical Food Section was used instead. ODG states that medical foods are dietary management for a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements. An online search showed that Sentra AM is a medical food that is intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome (PTSD), neurotoxicity-induced fatigue syndrome, and impaired neurocognitive functions. In this case, there is no documentation that this patient has the abovementioned conditions. Documentation does not provide the rationale for this request, or of any nutritional deficiencies in this patient. Therefore, the request for Sentra AM, sixty count, is not medically necessary or appropriate.

Sentra PM, sixty count: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation website tmedpharma.com (www.tmedpharma.com/docs/monographs-10-09/Sentra_PM_Monograph_v_Final_10-15-2009.pdf).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Sentra PM.

Decision rationale: The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, ODG was used instead. According to ODG, Sentra PM is intended for use in management of sleep disorders associated with depression. Sentra PM is a proprietary blend of choline, bitartrate, glutamate, and 5-hydroxytryptophan. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. Glutamic Acid is used for treatment of hypochlohydria and achlorhydria including those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. 5-hydroxytryptophan has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity, and sleep disorders. In this case, there is no indication regarding the rationale for this request. There is no discussion concerning sleep difficulty. There is also no documentation regarding nutritional deficiencies in this patient. Therefore, the request for Sentra PM, sixty count, is not medically necessary or appropriate.

Gabadone, sixty count: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation website tmedpharma.com (www.tmedpharma.com/docs/monographs-10-09/GABAdone_Monograph_UPDATED_FINAL_10-16%202009.pdf).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, GABAdone.

Decision rationale: The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, ODG was used instead. The Official Disability Guidelines also state that GABAdone is not recommended as it is a medical food. It is a proprietary blend of choline bitartrate, glutamic acid, 5-hydroxytryptophan, and GABA. It is intended to meet the nutritional requirements for inducing sleep, promoting restorative sleep, and reducing snoring in patient who are experiencing anxiety related to sleep disorders. There is no documentation regarding nutritional deficiencies, anxiety, or sleep difficulties in this patient. Also, this compound is not recommended for use. There is also no guideline recommendation supporting the use of this

product. Therefore, the request for Gabadone, sixty count, was not medically necessary or appropriate.

Terocin pain patch, twenty count: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines COMPOUND TOPICALS.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidocaine patch Page(s): 56-57.

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, there was no evidence that patient had failure of first-line therapy. There was no documented rationale for this request. Date of initiation likewise is unknown because there was no progress report citing prescription for Terocin patch. The medical necessity cannot be established due to insufficient information. Therefore, the request for Terocin pain patch, twenty count, is not medically necessary or appropriate.

Terocin 240 mg (Capsaicin 0.025%, Menthyl salicylate 25%, Menthol 10%, Lidocaine 2.5%): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines COMPOUND TOPICALS.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin, Topical Analgesics Page(s): 28-29, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Section, Topical Salicylates.

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, the Chronic Pain Medical Treatment Guidelines identify 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, the Chronic Pain Medical Treatment Guidelines 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 has been prescribed Terocin cream since May 2013.

However, there is no documentation concerning pain relief and functional improvement derived from its use. 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. Furthermore, there is no discussion concerning the need for multiple topical analgesics in this case. Therefore, the request for Terocin 240 mg (Capsaicin 0.025%, Menthyl salicyclate 25%, Menthol 10%, Lidocaine 2.5%) is not medically necessary or appropriate.

Flurbi (NAP) cream 180 gms (Flurbiprofen 20%, Lidocaine 5%, Amitriptyline 4%):
Upheld

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

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

Decision rationale: According to the 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 a topical compounded product since May 2013 for pain and inflammation. However, there is no documentation regarding any benefits derived from its use. Furthermore, there is no discussion concerning the need for three different topical medications in this case. In addition, components of this compound, i.e., flurbiprofen, lidocaine, and amitriptyline, 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. Therefore, the request for Flurbi (NAP) cream 180 gms (Flurbiprofen 20%, Lidocaine 5%, Amitriptyline 4%) is not medically necessary or appropriate.

Gabacyclotram 180 mgs (Gabapentin 10%, Cyclobenzaprine 6%, Tramadol 10%): Upheld

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

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

Decision rationale: According to the Chronic Pain Medical Treatment Guidelines, 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 a topical compounded product since May 2013 for pain and inflammation. However, there is no documentation regarding any benefits derived from its use. Furthermore, there is no discussion concerning the need for three different topical medications in this case. In addition, components of this compound, i.e., gabapentin,

cyclobenzaprine, and tramadol, 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. Therefore, the request for Gabacyclotram 180 mgs (Gabapentin 10%, Cyclobenzaprine 6%, Tramadol 10%) is not medically necessary or appropriate.

Genicin (glucosamine sodium 500 mg), ninety count: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine Page(s): 50.

Decision rationale: According to the Chronic Pain Medical Treatment Guidelines, Glucosamine is recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. In this case, patient was prescribed Genicin, a brand name of Glucosamine, since May 2013 for arthritic pain. However, there is no documentation concerning pain relief and functional improvement derived from its use. Therefore, the request for Genicin (glucosamine sodium 500 mg), ninety count, is not medically necessary or appropriate.

Somnicin (Melatonin 2mg, 5HTP 50mg, Tryptophan 100mg, Pyridoxine 10mg, Magnesium 50mg), thirty count: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation website RX Wiki (www.rxwiki.com/somnicin).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Insomnia Section.

Decision rationale: The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, Official Disability Guideline, Pain Chapter, Insomnia Section was used instead. ODG recommends that treatment of insomnia be based on etiology. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. In this case, patient was prescribed Somnicin since May 2013 for insomnia, anxiety, and muscle relaxation. However, there was no documentation concerning pain relief and functional improvement derived from its use. Moreover, there was no evidence of sleep hygiene in the records submitted. Therefore, the request for Somnicin (Melatonin 2mg, 5HTP 50mg, Tryptophan 100mg, Pyridoxine 10mg, Magnesium 50mg), thirty count, is not medically necessary or appropriate.