

Case Number:	CM14-0212233		
Date Assigned:	02/03/2015	Date of Injury:	01/23/2013
Decision Date:	03/05/2015	UR Denial Date:	12/02/2014
Priority:	Standard	Application Received:	12/18/2014

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: Maryland

Certification(s)/Specialty: Physical Medicine & Rehabilitation, Neuromuscular Medicine

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This is a 50 year old female who suffered an industrial related injury on 1/23/13. A physician's report dated 12/10/13 noted the injured worker sustained a work related injury to her head, cervical spine, bilateral shoulder, wrists and psyche due to continuous trauma from 11/1/11 to 11/15/13. The injured worker had complaints of headaches, neck pain, low back pain, bilateral shoulder pain, right wrist pain that radiated to the elbow, and left hand, middle finger, and thumb pain. Diagnoses included headache, cervical radiculitis, lumbar radiculopathy, bilateral shoulder internal derangement, left trigger finger, anxiety, insomnia, unspecified adjustment reaction, idiopathic peripheral autonomic neuropathy, and unspecified disorder of autonomic nervous system. A physician's report dated 9/22/14 noted the injured worker had complaints of headaches, neck pain radiating distally down the bilateral upper extremities with associated numbness and tingling. Left foot, bilateral shoulder pain, bilateral wrist pain, and bilateral hand pain associated with numbness was noted. The physical examination revealed tenderness to palpation along the trapezius muscles bilaterally with palpable spasms. Tenderness to palpation of the lumbar spine with palpable spasms along the paravertebral muscles bilaterally was also noted. Diagnoses included headaches, cervical disc degeneration, cervical radiculopathy, lumbar sprain/strain, lumbar disc protrusion, lumbar spinal stenosis, bilateral shoulder labral tear, right shoulder tendinitis, left shoulder osteoarthritis, right wrist sprain/strain, left trigger finger, left foot plantar fasciitis, and status post left toe fracture. The injured worker was prescribed Naproxen, Omeprazole, Terocin patches, Menthoderm Gel, Xolindo cream, Theramine, Sentra AM, Sentra PM, and Gabadone. On 12/2/14 the utilization review (UR) physician denied the

following requests. Regarding a urine drug screen, the UR physician noted there was no documentation of ongoing opioid treatment. Regarding topical Terocin 120ml, Flurbi (NAP) cream 180gm, Gabacyclotram 180gm, Terocin pain patch #20, Methoderm Gel #240, and Xoliindo 2% cream the UR physician noted evidence based guidelines do not consistently support compound medications including Ketoprofen, Lidocaine, Capsaicin, Baclofen, Gabapentin, or other antiepilepsy or muscle relaxant drugs for topical applications. Regarding Somnicin #30, the UR physician noted evidence based guidelines do not consistently support compounded medications or melatonin in the management of the cited injury/condition. Regarding Theramine #90, Sentra AM #60, Sentra PM #60, and Gabadone #60 the UR physician noted evidence based guidelines do not consistently support medical foods in the management of the cited injury/condition.

IMR ISSUES, DECISIONS AND RATIONALES

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

Toxicology - Urine drug screen: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Drug testing Page(s): 43.

Decision rationale: Urine drug screen is not medically necessary per the MTUS Guidelines. The MTUS states that when initiating opioids a urine drug screen to assess for the use or the presence of illegal drugs. The documentation does not reveal that the patient is taking opioid medication therefore a request for urine drug screen is not medically necessary.

Terocin 120ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 112-113. Decision based on Non-MTUS Citation <http://www.drugs.com/pro/terocin.html>

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics & Lidoderm & Methyl salicylate Page(s): 111-113 & 56-57 & 105.

Decision rationale: Terocin 120 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 topical agents. 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 is 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 is 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 and topical lidocaine in this case is not supported by the MTUS therefore the entire compounded product is not medically necessary. The request therefore for Terocin 120ml is not medically necessary

Flurbi (NAP) Cream - LA 180gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 112-113.

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

Decision rationale: Flurbi (NAP) Cream - LA 180gm is not medically necessary per the MTUS Chronic Pain Medical Treatment Guidelines. The MTUS guidelines state that there is little evidence to support the use of topical NSAIDS (flurbiprofen is an NSAID) for the treatment of osteoarthritis of the spine, hip, or shoulder . The guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Flurbi (NAP) also contains topical Lidocaine which is not supported by the MTUS in cream form. Also, this product contains Amitriptyline which the MTUS does not support for topical use. Furthermore the guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended therefore Flurbi (NAP) is not medically necessary.

Gabacyclotram 180mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 112-113.

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.

Somnicin #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation
<http://dailymed.nlm.nih.gov/dailymed/druginfo.cfm?id=35944>

MAXIMUS guideline: Decision based on MTUS ACOEM Page(s): Updated ACOEM Guidelines, Pain section; Complementary, alternative treatments, or dietary supplements, etc., page 135. Decision based on Non-MTUS Citation Pain

Decision rationale: Somnicin 30 is not medically necessary per ODG and the MTUS guidelines. The ACOEM 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 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.” Per the manufacturer, Somnicin is a hypnotic medication consisting of Melatonin, 5-HTP, Ltryptophan, Vitamin B6, and Magnesium. The documentation does not indicate that the patient has a unique requirement for this nutritional supplement. Therefore, the request for Somnicin 30 is not medically necessary.

Terocin pain patch #20: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 112-113. Decision based on Non-MTUS Citation
<http://www.drugs.com/otc/terocin/html>

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patch) Menthol & Topical analgesics Page(s): 56 & 105 and 111-112.

Decision rationale: Terocin patch is not medically necessary per MTUS Chronic Pain Medical Treatment Guidelines. A Terocin patch contains: Menthol 4%; Lidocaine 4%. Per MTUS guidelines, topical lidocaine in the form of a cream, lotion or gel is not indicated for neuropathic pain. The guidelines state that lidocaine in a patch form 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), and is only FDA approved for post-herpetic neuralgia. The MTUS guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Furthermore, the MTUS guidelines state that compounded products that contain at least one drug (or drug class) that is not recommended is not recommended. Although Menthol is not specifically addressed in the MTUS, menthol is present in Ben Gay which is recommended by the

MTUS. Due to the fact that documentation submitted does not show evidence of intolerance to oral medications, failure of first-line therapy and no indication of post-herpetic neuralgia in this patient Terocin patch is not medically necessary.

Menthoderm gel #240: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111. Decision based on Non-MTUS Citation <http://www.drugs.com/cdi/menthoder-cream.html>

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

Decision rationale: Mentoderm gel #240 is not medically necessary per the MTUS Chronic Pain Medical Treatment Guidelines. Mentoderm is Methyl Salicylate 15%/Menthol 10%. The documentation indicates that the patient has been using Mentoderm without evidence of functional improvement as defined by the MTUS. The MTUS states that salicylate are significantly better than placebo in chronic pain. The MTUS states that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. The documentation does not indicate intolerance of oral medications. The request does not specify what body part the gel is for. The request for Mentoderm gel is not medically necessary.

Xolindo 2% cream: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 112-113. Decision based on Non-MTUS Citation <http://www.dailymed.nlm.nih.gov/dailymed/druginfo.cfm?setid>

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

Decision rationale: Xolindo 2% cream is not medically necessary per the MTUS Chronic Pain Medical Treatment Guidelines. The MTUS states that topical formulations of lidocaine (whether creams, lotions or gels) are not indicated for neuropathic pain. The documentation does not indicate evidence of intolerance to oral medications. The documentation does not indicate extenuating circumstances to deviate from guideline recommendations. The request does not specify to what body part this will be applied. The request for Xolindo 2% cream is not medically necessary.

Theramine #90: 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) Pain Chapter

MAXIMUS guideline: Decision based on MTUS ACOEM Page(s): Updated ACOEM Guidelines, Pain section; Complementary, alternative treatments, or dietary supplements, etc., page 135. Decision based on Non-MTUS Citation Pain

Decision rationale: Theramine #90 is not medically necessary per the MTUS ACOEM Guidelines and the ODG. The ODG states that Theramine is not recommended for the treatment of chronic pain. Theramine is a medical food form that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. The ODG states that there is insufficient research to support the use of this product in chronic pain. The updated ACOEM and the ODG guidelines state that medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The documentation does not reveal any extenuating reasons to go against the recommended medical guidelines. The request for Theramine is not medically necessary.

Sentra AM #60: 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) Pain Chapter

MAXIMUS guideline: Decision based on MTUS ACOEM Page(s): Updated ACOEM Guidelines, Pain section; Complementary, alternative treatments, or dietary supplements, etc., page 135. Decision based on Non-MTUS Citation Pain (chronic)

Decision rationale: Sentra AM #60 is not medically necessary per the MTUS and updated ODG guidelines. The MTUS Guidelines do not address Sentra. The ODG guidelines state that Sentra AM is a medical food, intended for use in management of sleep disorders associated with depression, that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. The updated ACOEM and the ODG guidelines state that medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The documentation does not reveal any extenuating reasons to go against the recommended medical guidelines. The request for Sentra is not medically necessary.

Gabadone #60: 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) Pain Chapter

MAXIMUS guideline: Decision based on MTUS ACOEM Page(s): Updated ACOEM Guidelines, Pain section; Complementary, alternative treatments, or dietary supplements, etc., page 135. Decision based on Non-MTUS Citation Pain (Chronic)

Decision rationale: Gabadone #60 is not medically necessary per the MTUS ACOEM Guidelines and the DOG. The ODG states that Gabadone is not recommended. Gabadone is a medical food that is a proprietary blend of choline bitartrate, glutamic acid, 5-hydroxytryptophan, GABA, grape seed extract, griffonia extract, whey protein, valerian extract, ginkgo biloba and cocoa. It is intended to meet the nutritional requirements for sleep disorders and sleep disorders associated with insomnia.

Sentra PM #60: 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) Pain Chapter

MAXIMUS guideline: Decision based on MTUS ACOEM Page(s): Updated ACOEM Guidelines, Pain section; Complementary, alternative treatments, or dietary supplements, etc., page 135. Decision based on Non-MTUS Citation Pain (Chronic)

Decision rationale: Sentra PM #60 is not medically necessary per the MTUS and updated ODG guidelines. The MTUS Guidelines do not address Sentra. The ODG guidelines state that Sentra PM is a medical food, intended for use in management of sleep disorders associated with depression, that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. The updated ACOEM and the ODG guidelines state that medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The documentation does not reveal any extenuating reasons to go against the recommended medical guidelines. The request for Sentra is not medically necessary.