

Case Number:	CM14-0210180		
Date Assigned:	02/03/2015	Date of Injury:	07/16/2013
Decision Date:	03/03/2015	UR Denial Date:	11/20/2014
Priority:	Standard	Application Received:	12/15/2014

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: Pennsylvania
 Certification(s)/Specialty: Internal 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:

The injured worker is a 38 year old male with a date of injury of 7/15/13. The mechanism of injury was noted as secondary to carrying a toilet for 200 feet with injury to the low back. Diagnoses included lumbar radiculopathy, idiopathic peripheral autonomic neuropathy, and unspecified disorder of autonomic nervous system. The injured worker had no significant past medical history. A report from the primary treating physician of September 3, 2014 notes that he was initially on light duty for approximately three months. In December of 2013, he reported persistent pain and discomfort, difficulty sleeping due to pain, and stress and anxiety as a result of the back pain. He had attended physical therapy for three sessions. At the 9/3/14 visit, pain was rated as 4 out of 10 in severity and relieved with medication patches. Examination showed decreased range of motion of the lumbar spine, positive straight leg raise bilaterally, and normal lower extremity strength, sensation, and reflexes. Work status was noted to be working full-time duty. He was not taking medication at the time of the 9/3/14 visit. Acupuncture, chiropractic treatment, physical therapy, TENS unit, autonomic function testing, MRI of the lumbar spine, and laboratory tests were requested, and multiple medications were prescribed. The physician documentation notes that transdermal topical medications were recommended in order to allow reduction in the total amount of oral medications required. Work restriction of no lifting was specified at that visit. On 9/15/14 a magnetic resonance imaging (MRI) of the lumbar spine showed scoliosis, disc dessication at L4-5 and L5-S1, with focal central disc protrusion and neuroforaminal narrowing at L4-5 and L5-S1. On 11/4/14, Utilization Review non-certified requests for terocin 120 ml, flubi (NAP) cream LA 180 gms, gabacyclotram 180 mgs, genicin

#90 capsules, somnicin #30 capsules, menthoder gel 120 gm, calypxo cream 113 gm, theramine #90, gabadone #60, and trepadone #120, citing the MTUS.

IMR ISSUES, DECISIONS AND RATIONALES

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

Terocin 120 ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines salicylates topical, topical analgesics Page(s): 104, 111-113. Decision based on Non-MTUS Citation Lexicomp 1987-2015: Camphor and Menthol: Drug Information

Decision rationale: Terocin is a compounded topical medication which contains methylsalicylate, capsaicin, menthol, and lidocaine. Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. The injured worker had diagnoses of lumbar radiculopathy and peripheral neuropathy. Topical salicylates are recommended for use for chronic pain. Capsaicin is recommended as an option in patients who have not responded or are intolerant to other treatments. It may be used for treatment of osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in high doses. The MTUS and ODG are silent with regard to menthol. It may be used for relief of dry, itchy skin, which was not documented in this injured worker. This agent carries warnings that it may cause serious burns. Lidocaine is only FDA approved for treating post-herpetic neuralgia, and the dermal patch form (Lidoderm) is the only form indicated for neuropathic pain. There was no documentation of a diagnosis of post-herpetic neuralgia for this injured worker. No other commercially approved topical formulations of lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain. Non-dermal patch forms are generally indicated as local anesthetics or anti-pruritics. The documentation submitted did not indicate that the injured worker had failed a trial of oral antidepressant or antiepileptic medication. The request for Terocin 120 ml is not medically necessary.

Flurbi (NAP) cream-LA 180 gms: 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): p.111-113.

Decision rationale: Flurbi (NAP) cream-LA is a topical nonsteroidal (NSAID) containing flurbiprofen. Topical NSAIDs are indicated for osteoarthritis and tendinitis, in particular that of the knee and elbow or other joints that are amenable to topical treatment. There is little evidence

to utilize topical NSAIDS for treatment of osteoarthritis of the spine, hip, or shoulder. Topical nonsteroidals are not recommended for neuropathic pain. The injured worker has diagnoses of lumbar radiculitis and peripheral neuropathy. No diagnosis of osteoarthritis was documented. The request for Flurbi (NAP) cream-LA 180 gms is therefore not medically necessary.

Gabaclotram 180 mgs: 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): p.111-113.

Decision rationale: Gabaclotram is a compounded topical medication containing gabapentin, cyclobenzaprine, and tramadol. Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. Gabapentin is an antiepileptic drug and is not recommended in topical form; there is no peer-reviewed literature to support use. Cyclobenzaprine is a muscle relaxant. Tramadol is a synthetic opioid usually used in oral form. The MTUS notes that there is no evidence for use of muscle relaxants as topical products. The documentation submitted did not indicate that the injured worker had failed a trial of oral antidepressant or antiepileptic medication. In addition, because this compounded product contains gabapentin and cyclobenzaprine which are not recommended in topical form, the compound is not recommended. The request for gabaclotram 180 mgs is not medically necessary.

Genicin #90 capsules: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines glucosamine and chondroitin Page(s): p.50.

Decision rationale: Genicin contains glucosamine. Per the MTUS, glucosamine and chondroitin sulfate are recommended as an option in patients with moderate arthritis pain, especially for knee osteoarthritis. The injured worker has a diagnosis of lumbar radiculopathy with MRI findings consistent with this diagnosis, and peripheral neuropathy. No diagnosis of osteoarthritis in general or osteoarthritis of the knee in particular was documented. The request for genicin #90 is not medically necessary.

Somnicin #30 capsules: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guideline

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG head: melatonin ODG chronic pain: insomnia treatment

Decision rationale: Somnicin is a medication for sleep which contains melatonin in addition to vitamins 5-HTP (hydroxytryptophan), L-tryptophan, vitamin B6, and magnesium. Per the ODG, melatonin is recommended in treating sleep disorder post-traumatic brain injury. The injured worker had no history of traumatic brain injury. For the treatment of insomnia, pharmacologic agents should only be used after careful evaluation of potential causes of sleep disturbance. Specific components of insomnia should be addressed. The injured worker reported difficulty sleeping due to pain. There was no documentation of evaluation of sleep disturbance in the injured worker, and components insomnia were not addressed. The request for somnicin # 30 is not medically necessary

Menthoderm Gel 120 gm: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines salicylates, topical analgesics Page(s): 104, 111-113. Decision based on Non-MTUS Citation Lexicomp 1978-2015 Camphor and Menthol: Drug information

Decision rationale: Mentoderm is a compounded topical medication containing methyl salicylate and menthol. These ingredients are also contained in Terocin and Calypxo, which were additional requested medications, making treatment duplicative. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. Topical salicylates are recommended for use for chronic pain. The MTUS and ODG are silent with regard to menthol. It may be used for relief of dry, itchy skin, which was not documented in this injured worker. This agent carries warnings that it may cause serious burns. Due to the potential for adverse effects from menthol, as well as the duplicative nature of the requests, the request for Mentoderm gel 120gm is not medically necessary.

Calypxo Cream 113 gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines salicylates topical, topical analgesics Page(s): p. 104, 111-113. Decision based on Non-MTUS Citation Lexicomp 1978-2015 Camphor and Menthol: Drug information

Decision rationale: Calypxo is a compounded topical medication containing methyl salicylate and menthol. These ingredients are also contained in Terocin and Mentoderm, which were additional requested medications, making treatment duplicative. If any compounded product

contains at least one drug or drug class that is not recommended, the compounded product is not recommended. Topical salicylates are recommended for use for chronic pain. The MTUS and ODG are silent with regard to menthol. It may be used for relief of dry, itchy skin, which was not documented in this injured worker. This agent carries warnings that it may cause serious burns. Due to the potential for adverse effects from menthol, as well as the duplicative nature of the requests, the request for Calypxo Cream 113 gm 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 Guideline

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Chronic pain chapter: Theramine

Decision rationale: Theramine is a medical food that contains 5-hydroxytryptophan 95%, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine, gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa (theobromine 6%). It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. Although the injured worker does have report of ongoing pain issues and peripheral neuropathy, per the ODG, Theramine is not recommended for the treatment of chronic pain. The request for Theramine #90 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 Guideline

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG chronic pain chapter: Gabadone

Decision rationale: GABAdone is a Medical food from [REDACTED], [REDACTED], 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. The physician notes that the injured worker reported sleep disturbance secondary to pain. Per the ODG, GABAdone is not recommended for sleep disorders based on limited available research. The request for Gabadone #60 is not medically necessary.

Trepadone #120: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guideline

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS.
Decision based on Non-MTUS Citation Chronic pain chapter: trepadone

Decision rationale: Trepadone is a medical food that is suggested for use in the management of joint disorders associated with pain and inflammation. It is a proprietary blend of L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan, L-serine, gamma-aminobutyric acid, grape seed extract, cinnamon bark, cocoa, omega-3 fatty acids, histidine, whey protein hydrolysate, glucosamine, chondroitin and cocoa. The injured worker has diagnoses of lumbar radiculopathy and peripheral neuropathy. Per the ODG, Trepadone is not recommended, as there is insufficient evidence to support use for osteoarthritis or for neuropathic pain. The request for Trepadone #120 is not medically necessary.