

Case Number:	CM15-0006551		
Date Assigned:	01/26/2015	Date of Injury:	09/04/2012
Decision Date:	04/10/2015	UR Denial Date:	01/08/2015
Priority:	Standard	Application Received:	01/12/2015

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: California, District of Columbia, Maryland
 Certification(s)/Specialty: Anesthesiology, Pain Management

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 48-year-old female, who sustained an industrial injury on 9/4/12. She has reported bilateral foot and ankle pain working as a waitress with repetition. The diagnoses have included contusion of ankle bilateral and pain in joint bilaterally. Treatment to date has included medications, diagnostics, conservative measures, and physical therapy. Currently, the injured worker complains of bilateral foot pain constant pain, which is debilitating. The foot pain with medication is 4/10 and without medication is 8/10. The bilateral feet reveal no evidence of swelling and have full range of motion noted. Magnetic Resonance Imaging (MRI) of the right ankle and left ankle and right foot dated 12/13/12 revealed periarticular soft tissues are unremarkable. The Magnetic Resonance Imaging (MRI) of the left foot dated 12/13/12 revealed a cyst in the lateral aspect of the navicular bone, likely degeneration in origin. The treating physician recommended topical compounds and creams to reduce need for prescription oral medications. On 1/8/15 Utilization Review non-certified a request for Somnicin 2mg # 30, Laxcin # 100, Gabacycloclotran cream 180gms # 1, Flurbi-cream 180gms # 1, Terocin cream 240mg # 1, and Terocin patches # 30, noting that regarding the Somnicin 2mg there are no subjective complaints regarding a sleep condition and the record do not establish a disease or condition for which distinctive nutritional requirements are established by medical evaluation. Regarding the Laxcin # 100, the records do not establish subjective complaints, objective findings or a diagnosis of constipation to support the requested medication. Regarding the Gabacycloclotran cream 180gms, the cyclobenzaprine component of the requested compound is not recommended. Regarding the Flurbi-cream 180gms, any compound product that contains at least one drug that

is not recommended is not recommended, in this case flurbiprofen is not recommended. Regarding the Terocin cream 240mg and Terocin patches # 30, the records do not support the injured worker has a diagnosis of peripheral neuropathy and has failed a trial of first line therapies , or is intolerant to other treatments. The (MTUS) Medical Treatment Utilization Schedule, (ACOEM) Occupational Medicine Practice Guidelines and Official Disability Guidelines (ODG) were cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

Somnicin 2mg # 30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter : Medical Foods; <http://www.prlog.org>.

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

Decision rationale: Somnicin is a compound of magnesium oxide, melatonin, oxitriptan, and tryptophan. Melatonin is recommended as an option for sleep disorder post-TBI. There is no other known benefit for the injured employees condition with the usage of magnesium oxide, oxycodone 10, and tryptophan. Additionally, per the California MTUS guidelines when one ingredient of a compound is not certified the entire compound is not certified. Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually. As such, this request for Somnicin is not medically necessary.

Laxcin # 100: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.dailymed.nlm.nih.gov>.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 - 9792.26; MTUS Page(s): 98, 99 of 127.

Decision rationale: Laxacin is a combination of ducosate and sennosides and is commonly prescribed for constipation. However, the injured employs not stated to have any of these current

issues. Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually. As such, this request for Laxacin and is not medically necessary.

Gabacloctran cream 180gms # 1: 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): 56, 111, 112 of 127.

Decision rationale: Gabacloctram is a topical preparation that contains gabapentin, cyclobenzaprine, and tramadol. The MTUS notes that the use of topical medications are largely experimental and there have been few randomized controlled trials. It further goes on to note that topical muscle relaxers and gabapentin are not recommended clinically indicated. Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually. As this compound contains both gabapentin and cyclobenzaprine, this request is considered not medically necessary and is recommended for noncertification.

Flurbi-cream 180gms # 1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 - 9792.26; MTUS (Effective July 18, 2009) Page(s): 111-112 of 127.

Decision rationale: The California MTUS guidelines support topical NSAIDs for the short-term treatment of osteoarthritis and tendinitis for individuals unable to tolerate oral non-steroidal anti-inflammatories. The guidelines support 4-12 weeks of topical treatment for joints that are

amendable topical treatments; however, there is little evidence to support treatment of osteoarthritis of the spine, hips or shoulders. When noting the injured employee's diagnosis, date of injury and clinical presentation, this request is not considered medically necessary.

Terocin cream 240mg # 1: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 49. Decision based on Non-MTUS Citation <http://www.drugs.com>.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113 of 127..

Decision rationale: Terocin topical pain lotion is a topical analgesic ointment containing Methyl Salicylate 25%, Capsaicin 0.025%, Menthol 10%, and Lidocaine 2.50%. Capsaicin does not have in indication for the injured employees diagnosis of a ankle/foot sprain. Methyl salicylate may have an indication for chronic pain in this context. However, the CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of menthol. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently implies a lack of recommendation, or a status equivalent to "not recommended". Since menthol is not medically indicated, the overall product is not indicated per MTUS as outlined below. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication." Therefore, it would be optimal to trial each medication individually.

Terocin patches # 30: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 49. Decision based on Non-MTUS Citation <http://www.drugs.com>.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113 of 127..

Decision rationale: Terocin patches are a topical medication containing Methyl Salicylate 25%, Capsaicin 0.025%, Menthol 10%, and Lidocaine 2.50%. Capsaicin does not have in indication for the injured employees diagnosis of a ankle/foot sprain. Methyl salicylate may have an indication for chronic pain in this context. Per MTUS p105, "Recommended. Topical salicylate (e.g., Ben-Gay, methyl salicylate) is significantly better than placebo in chronic pain. (Mason-BMJ, 2004)." However, the CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of menthol. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently

implies a lack of recommendation, or a status equivalent to "not recommended". Since menthol is not medically indicated, then the overall product is not indicated per MTUS as outlined below. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually.