

<b>Case Number:</b>	CM13-0006026		
<b>Date Assigned:</b>	06/20/2014	<b>Date of Injury:</b>	04/24/1996
<b>Decision Date:</b>	07/29/2014	<b>UR Denial Date:</b>	07/08/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/01/2013

### 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 Hawaii. 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:

The patient is a 49-year-old male employee with a date of injury on April 24, 1996. A review of the medical records indicate that the patient is undergoing treatment for low back pain, thoracolumbar radiculitis, and failed back syndrome. Subjective complaints (3/25/2014) include 7/10 constant back pain with radiation to right lower extremity. Objective findings (3/25/2014) include decreased thoracic and lumbar range of motion. Treatment has included Ambien 10mg (since at least 2011), amitriptyline 25mg, lumbar facet block, neuro-stim implant (9/2012), Terocin, Flurbiprofen 20%, Lidocaine %, Amitriptyline 4% compound cream, and GabaCycloTram. A utilization review dated 7/8/2013 noncertified the requests for: 1) Prescription of Flurbiprofen 20%, Lidocaine 5%, Amitriptyline 4% compound cream, 2) Prescription of Terocin 240mL: Capsaicin 0.025%, Menthol 2%, Lidocaine 3) Ambien 10mg, #30 4) Prescription of GabaCycloTram 180gm: Gabapentin 10%, Cyclobenzaprine 6%, Tramadol 10%: 5) Genicin 500mg, #90 6) Somnicin #30: Melatonin 2mg, 5HTP 50mg, L Tryptophan 100mg, Pyridoxine 10mg, Magnesium 50mg.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Prescription of Flurbiprofen 20%, Lidocaine %, Amitriptyline 4% compound cream:**  
Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen, Topical Analgesics page(s) 72, 111-113 Page(s): ) 72, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Topical analgesics.

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines state that there is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The Official Disability Guidelines recommends usage of topical analgesics as an option, but also further details primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Medical documents provided do not indicate failed trials of his amitriptyline. Lidocaine is also used for Neuropathic pain with guidelines recommending it 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). Medical records do not indicate failed trials of gabapentin or Lyrica. As such, the request is not medically necessary.

**Prescription of Terocin 240ml: Capsacin 0.025%, Menthol 2%, Lidocaine:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm patches, Topical analgesics Page(s): 56-57, 111. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Topical analgesics; as well as the Non-MTUS website UpToDate.com, Lidocaine (topical).

**Decision rationale:** Terocin is a topical pain medication that contains lidocaine and menthol. The Official Disability Guidelines state that lidocaine topical patch is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. Medical documents do not document the patient as having post-herpetic neuralgia. Additionally, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is no documentation that indicates the patient failed the trial of amitriptyline. Guidelines state that there is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Lidocaine is not supported by the treatment guidelines. As such, the request is not medically necessary at this time.

**Prescription of Ambien 10mg, #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 (ODG), Pain (chronic) chapter, Zolpidem (Ambien).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines, Page 24 Page(s): 24. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Insomnia Treatment.

**Decision rationale:** The California MTUS Guidelines and the Official Disability Guidelines state that zolpidem is a prescription short acting non-benzodiazepine hypnotic, which is approved for short-term treatment of insomnia. In this case, the patient has been taking this medication as early as 2011, which far exceeds guidelines recommendations. There has been no discussion of the patient's sleep hygiene or the need for variance from the guidelines, such as a) Wake at the same time everyday; (b) Maintain a consistent bedtime; (c) Exercise regularly (not within 2 to 4 hours of bedtime); (d) Perform relaxing activities before bedtime; (e) Keep your bedroom quiet and cool; (f) Do not watch the clock; (g) Avoid caffeine and nicotine for at least six hours before bed; (h) Only drink in moderation; & (i) Avoid napping. Medical documents also do not include results of these first line treatments, if they were used in treatment of the patient's insomnia. The Official Disability Guidelines additionally states that the specific component of insomnia should be addressed: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; & (d) Next-day functioning. Medical documents provided do not detail these components. As such, the request is not medically necessary at this time.

**Prescription of GabaCycloTram 180gm: Gabapentin 10%, Cyclobenzaprine 6%, Tramadol 10%: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, page(s) 111-113 Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Topical Analgesics.

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines on Topical Analgesics indicates that topical medications are largely experimental in use with few randomized controlled trials to determine efficacy or safety. These are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. In this case, the medical records provided do not endorse failure of his amitriptyline. It is also noted this particular formulation contains agents that are not recommended for topical use under guidelines, specifically Tramadol and Gabapentin. The guidelines also indicate that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. There is no evidence for use of antiepilepsy drugs as a topical product, nor is there evidence for efficacy and safety of topical Tramadol. As such, the request is not medically necessary.

**Prescription of Genicin 500mg, #90: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate), page(s) 50 Page(s): 50. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Guidelines Glucosamine (and Chondroitin Sulfate).

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines recommended Glucosamine (and Chondroitin Sulfate) as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Medical documents do not indicate that the patient is undergoing treatment for arthritis pain. As such, the request is not medically necessary.

**Prescription of Somnicin #30: Melatonin 2mg, 5HTP 50mg, L Tryptophan 100mg, Pyridoxine 10mg, Magnesium 50mg: Upheld**

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

**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), Medical Food; as well as the Non-MTUS Somnicin-Patient-Info-Sheet ([sales.advancedrxmgt.com](http://sales.advancedrxmgt.com)).

**Decision rationale:** The California MTUS Guidelines are silent regarding Somnicin. Somnicin is classified as medical food, which is formulated to be consumed or administered entirely 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. The package inserts indicates that Somnicin is a 'natural sleep aid that helps and promotes sleep and contains Melatonin 2mg, 5-HTP (5-Hydroxytryptophan) 50mg, L-tryptophan 100mg, Vitamin B6 (pyridoxine) 10mg, and Magnesium 50 mg. Medical documents do not establish deficiency in nutritional requirements and do not indicate how the requested medication would specifically address the deficiency. As such, the request is not medically necessary.