

<b>Case Number:</b>	CM15-0067521		
<b>Date Assigned:</b>	04/22/2015	<b>Date of Injury:</b>	03/08/2010
<b>Decision Date:</b>	09/01/2015	<b>UR Denial Date:</b>	03/19/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/09/2015

### 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: New York  
 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 59-year-old female, who sustained an industrial injury on 3/8/10. She reported neck pain that radiated to right upper extremity and headaches. The injured worker was diagnosed as having cervical trapezius strain and sprain, thoracolumbar strain and sprain with left lower extremity radicular symptoms, status post right carpal tunnel release and right their finger trigger point injection, left knee patellofemoral arthritis, and status post right shoulder rotator cuff repair. Treatment to date has included cervical epidural block injections and medication. Currently, the injured worker complains of pain in the cervical spine with radiation to bilateral shoulders and upper extremities. Right wrist and left knee pain was also noted. The treating physician requested authorization for Ondansetron 8mg #10 (3 bottles), Genicin #90, Laxacin #100, compound ointment: Gabapentin/Cyclobenzaprine/Tramadol cream 180g, Terocin patch #30, Terocin cream 240ml, and Somnicin #30.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Ondansetron 8mg #10 (3 bottles): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MedlinePlus - Ondansetron.

**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-- Antiemetics (for opioid nausea).

**Decision rationale:** Ondansetron (Zofran) is used to prevent nausea and vomiting that may be caused by anesthesia/surgery, or chemotherapy or radiation therapy. It is also approved for use acutely with gastroenteritis. Ondansetron is not used and is ineffective for nausea associated with narcotic analgesics. In this case, the guidelines for its use are not met, which would also make the request for Ondansetron not medically necessary.

**Genicin #90:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation drugs.com - Genicin (Glucosamine) Medical Facts.

**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 - Chondroitin/Glucosamine.

**Decision rationale:** As per ODG Criteria it is recommended as an option (glucosamine sulfate only) given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride (GH). For all herbals and dietary supplements, there may be concerns for potential interactions with prescription and over-the-counter medications and lack of manufacturing quality controls. In this case, within the submitted documentation it is not clear how long injured worker has been using Genicin and what is the functional improvement. In addition, there is no mention of frequency and dosage. Based on the currently available information, the medical necessity for Genicin has not been established. The requested treatment is not medically necessary.

**Laxacin #100:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation fdb.rxlist.com/drugs/drug - Laxacin oral drug information on Uses, Side Effects.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Opioid-induced constipation treatment.

**Decision rationale:** According to ODG, if opioids are determined to be appropriate for the treatment of pain then prophylactic treatment of constipation should be initiated. First-line: When prescribing an opioid, and especially if it will be needed for more than a few days, there

should be an open discussion with the patient that this medication may be constipating, and the first steps should be identified to correct this. Simple treatments include increasing physical activity, maintaining appropriate hydration by drinking enough water, and advising the patient to follow a proper diet, rich in fiber. These can reduce the chance and severity of opioid-induced constipation and constipation in general. In addition, some laxatives may help to stimulate gastric motility. Other over-the-counter medications can help loosen otherwise hard stools, add bulk, and increase water content of the stool. Second-line: If the first-line treatments do not work, there are other second-line options. About 20% of patients on opioids develop constipation, and some of the traditional constipation medications do not work as well with these patients, because the problem is not from the gastrointestinal tract but from the central nervous system, so treating these patients is different from treating a traditional patient with constipation. In this case, of injured worker, discussion about first line treatment cannot be located within the submitted medical records. Also within the submitted documentation, it is not clear how long injured worker has been using Laxacin and what is the functional improvement. There is no mention of frequency and dosage. Based on the currently available information, the medical necessity for Laxacin has not been established. The requested treatment is not medically necessary.

**Compound Ointment: Gabapentin/Cyclobenzaprine/Tramadol Cream, 180 Grams:** 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): 111 to 113.

**Decision rationale:** According to the California MTUS Guidelines, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, local anesthetics or antidepressants. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case, there is no documentation provided necessitating Gabapentin. MTUS states that Gabapentin is not recommended topically. There is no peer-reviewed literature to support use. Medical necessity for the requested topical medication has not been established. The requested treatment: Compound Ointment: Gabapentin/Cyclobenzaprine/Tramadol Cream, 180 Grams is not medically necessary.

**Terocin patch #30:** 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): 111 to 113.

**Decision rationale:** According to the California MTUS Guidelines, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, local anesthetics or antidepressants. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case there is no documentation provided necessitating Terocin. This medication contains methyl salicylate, capsaicin, menthol, and lidocaine. MTUS states that capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. There is no documentation of intolerance to other previous medications. The treating provider's notes are not clear about using both cream and patch. Medical necessity for the requested topical medication has not been established. The requested treatment Terocin patch is not medically necessary.

**Terocin Cream 240ml:** 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): 111 to 113.

**Decision rationale:** According to the California MTUS Guidelines, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, local anesthetics or antidepressants. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case there is no documentation provided necessitating Terocin. This medication contains methyl salicylate, capsaicin, menthol, and lidocaine. MTUS states that capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. There is no documentation of intolerance to other previous medications. The treating provider's notes are not clear about using both cream and patch. Medical necessity for the requested topical medication has not been established. The requested treatment Terocin patch 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 Official Disability Guidelines, Pain, Somnicin.

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

**Decision rationale:** ODG states that dietary supplements/ vitamins are intended for specific dietary management of disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. ODG further states that medical food is not recommended. Somnicin contains certain ingredients, among them are Melatonin, 5-HTP, L-tryptopan, Vitamin B6 and Magnesium. Review of medical records mention neither any rationale, nor any documentation of deficiency. In this case, within the submitted documentation it is not clear how long injured worker has been using Somnicin and what is the functional improvement. Based on the currently available information and guidelines, the medical necessity for Somnicin has not been established. The requested treatment is not medically necessary.