

<b>Case Number:</b>	CM13-0017752		
<b>Date Assigned:</b>	10/11/2013	<b>Date of Injury:</b>	04/11/2007
<b>Decision Date:</b>	01/30/2014	<b>UR Denial Date:</b>	08/08/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/28/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Family Practice and is licensed to practice in Texas. 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 physician 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 39-year-old female who reported an injury on 04/11/2007. The mechanism of injury was not provided for review. The patient was treated with multiple forms of conservative treatment culminating into the decision to undergo lumbar fusion at the L5-S1. The patient's pain continued to be managed with medications. The patient's most recent physical evaluation revealed the patient continued to have significant low back pain radiating into the right lower extremity across the S1 distribution. It was noted that the patient had a straight leg raising test that was positive bilaterally and increased sensation across the S1 distribution. The patient's diagnoses included lumbar discogenic disease, bilateral S1 radiculopathy, right knee tendinitis, and left knee compensatory injury. The treatment plan included a lumbar fusion, trigger point injections, an MRI of the left knee, a stabilizing brace of the right knee, and a Toradol injection.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Terocin patch and cream:** 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.

**Decision rationale:** The requested Terocin patch and cream are not medically necessary or appropriate. The patient continues to have chronic low back pain radiating into the right lower extremity. The requested Terocin cream and patch contain methyl salicylate, capsaicin, menthol, and lidocaine. California Medical Treatment Utilization Schedule does recommend the use of methyl salicylate and menthol as a topical agent. However, the use of capsaicin is only recommended for patients who are intolerant or unresponsive to other treatments. The clinical documentation submitted for review does not provide any evidence that the patient has been unresponsive or intolerant to other treatments to include oral analgesics. Additionally, California Medical Treatment Utilization Schedule states that, "No other commercially approved topical formulation of lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain." Also, the California Medical Treatment Utilization Schedule recommends the introduction of pain medications for the management of chronic pain be introduced 1 at a time. Therefore, a formulation of medication with multiple medications would not be indicated. As the compounded agent contains at least 1 element that is not recommended by guideline recommendations, this medication would not be supported. As such, the requested Terocin patch and cream are not medically necessary or appropriate.

**Flurbi cream:** 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.

**Decision rationale:** The requested Flurbi Cream is not medically necessary or appropriate. The clinical documentation submitted for review does provide evidence that the patient has pain that radiates into the lower extremities. California Medical Treatment Utilization Schedule does not recommend the use of nonsteroidal anti-inflammatory drugs as topical agents unless oral agents are not tolerated or contraindicated by the patient. The clinical documentation submitted for review does not provide any evidence that the patient cannot take oral nonsteroidal anti-inflammatory drugs. As such, the requested Flurbi Cream would not be medically necessary or appropriate.

**Gabacyclotram cream:** 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.

**Decision rationale:** The requested Gabacyclotram Cream is not medically necessary or appropriate. The patient does have significant low back pain radiating into the lower extremities. However, California Medical Treatment Utilization Schedule does not recommend Gabapentin or Cyclobenzaprine as a topical agent due to lack of scientific evidence to support the efficacy of

these medications as topical agents. Additionally, peer reviewed literature does not support opioids such as tramadol as a topical agent due to lack of scientific evidence to support the efficacy of this medication. California Medical Treatment Utilization Schedule recommends medications be introduced singularly when being used to manage a patient's chronic pain. Therefore, a compounded agent would not be supported by guideline recommendations. As such, the requested Gabacyclotram Cream is not medically necessary or appropriate

**Genicin caps:** 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 Chapter, Medical Food.

**Decision rationale:** The requested Genicin Caps are not medically necessary or appropriate. The clinical documentation submitted for review does provide evidence that the patient has significant continued pain complaints radiating into the lower extremities. The requested medication is considered medical food. The clinical documentation submitted for review does not provide any nutritional deficits that would benefit from medical food. Therefore, the requested Genicin Caps are not medically necessary or appropriate

**Laxacin tabs:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mosby's Drug Consult

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Initiating Opioid Therapy Page(s): 77.

**Decision rationale:** The requested Laxacin Tabs are not medically necessary or appropriate. The clinical documentation submitted for review does provide evidence that the patient has chronic low back pain radiating into the lower extremities. California Medical Treatment Utilization Schedule recommends prophylaxis for constipation when initiating opioid therapy. However, the clinical documentation submitted for review does not provide any evidence that the patient is taking any oral medications that would cause constipation. Additionally, this medication is not supported by any deficits noted within the documentation to support the medical necessity of this drug. As such, the requested Laxacin Tabs are not medically necessary or appropriate

**Somnicin caps:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, compound drugs.

**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, Medical Food.

**Decision rationale:** The requested Somnicin Caps are not medically necessary or appropriate. The clinical documentation submitted for review does provide evidence that the patient has continued low back pain radiating into the lower extremities. Official Disability Guidelines recommend medical food as an alternative to medications to manage chronic symptoms. The requested medication is generally used to assist with insomnia and mood disturbances. The clinical documentation submitted for review does not provide any evidence that the patient suffers from any sleep disturbances or mood disorders that would benefit from this medical food. Additionally, there is no documentation that the patient has failed to respond to non-pharmacological methods to improve sleep hygiene. As such, the requested Somnicin Caps are not medically necessary or appropriate.