

<b>Case Number:</b>	CM14-0004522		
<b>Date Assigned:</b>	02/05/2014	<b>Date of Injury:</b>	07/18/2007
<b>Decision Date:</b>	06/25/2014	<b>UR Denial Date:</b>	01/09/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/13/2014

### 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. The expert reviewer is Board Certified in Physical Medicine and Rehabilitation 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 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 injured worker is a 65-year-old male with a reported date of injury on 07/18/2007. The mechanism of injury was not provided within the documentation available for review. The injured worker complained of pain in the lumbar spine, and residual pain in the right knee post total knee arthroplasty. An MRI of unknown date, revealed multiple disc protrusions at L2-3, L3-4, L4-5, and L5-S1, with severe foraminal stenosis noted at L3-4, L4-5, and at L5-S1. The injured worker's diagnoses included lumbar discopathy, and musculoligamentous injury status post total right knee arthroplasty. The injured worker's medication regimen included Norco. The request for authorization for Terocin patch #30, flurbi (NAP) cream-LA 180, gabacyclotram 180, laxacin tablet #100, and Somnicin cap #30 was submitted on 01/13/2014. However, the rationale was not provided for review.

### IMR ISSUES, DECISIONS AND RATIONALES

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

#### **TEROCIN PATCH # 30:** 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): 111-112.

**Decision rationale:** Terocin patches contain lidocaine and menthol. According to The California MTUS Guidelines, topical analgesics are recommended as an option. Topical analgesics are largely experimental in use with few randomized control trials to determine effectiveness or safety. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Lidocaine has been recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy. Topical lidocaine, in the formulation of a dermal patch called Lidoderm, has been designated for orphan status by the FDA for neuropathic pain. No other commercially approved topical formulations of lidocaine are recommended for neuropathic pain. As Terocin contains lidocaine and menthol, this does not meet the recommended guidelines. In addition, the request as submitted failed to specify a site in which the Terocin patch was to be utilized. Therefore, the request for Terocin patch is not medically necessary.

**FLURBI (NAP) CREAM-LA 180:** 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, non-steroidal anti-inflammatory agents (NSAIDs) Page(s): 111.

**Decision rationale:** The effectiveness of nonsteroidal anti-inflammatories in recent clinical trials has been inconsistent and most studies are small and short of duration. Topical NSAIDs have been shown to maximize effect in the first 2 weeks of treatment for osteoarthritis with a diminishing effect over another 2 week period. Topical NSAIDs are recommended for short-term use (4 to 12 weeks). There is little evidence to utilize topical NSAIDs for the treatment of osteoarthritis of the spine, hip, or shoulder. The request as submitted failed to provide the frequency and the specific site at which the Flurbi (NAP) cream-LA was to be utilized. According to the guidelines, NSAIDs are not recommended for treatment of osteoarthritis of the spine, hip or shoulder. According to the documentation provided for review, the injured worker's complaints are mainly around the lumbar spine. The request as submitted failed to provide the frequency of the medication. Therefore, the request for Flurbi (NAP) cream-LA #180 is not medically necessary.

**GABACYCLOTRAM 180:** 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): 111-113.

**Decision rationale:** According to the California MTUS Guidelines topical analgesics are recommended as an option and are largely experimental in use with few randomized control trials to determine effectiveness or safety. Primarily recommended for neuropathic pain when trials of antidepressant and anticonvulsants have failed. There is little to no research to support

the use of compounded these agents. The use of these comounded agents requires knowledge fo the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. Gabaclyclotram contains gabapentin. According to the California MTUS Guidelines gabapentin is not recommended. There is no peer-reviewed literature to support the use of gabapentin. In addition, the request as submitted failed to provide the frequency or the specific site at which the gabaclyclotram would be utilized. Therefore, the request for gabcyclotram #180 is not medically necessary.

**LAXACIN TABLET # 100:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines Opioids, criteria for use Page(s): 77.

**Decision rationale:** According to the California MTUS Guidelines prophylactic treatment for constipation is recommended when initiating treatment with opioids. According to the documentation provided for review, the injured worker is not initiating opioid use. In addition, there was a lack of documentation related to complaints of constipation. The rationale for the request was not provided within the documentation available for review. The frequency was not provided in the request. Therefore, the request for Laxacin tablet #100 is not medically necessary.

**SOMNICIN CAP # 30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://sales.advancedrxmgt.com/sales-content/uploads/2012/04/Somnicin-Patient-Info-Sheet.pdf>.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines Antidepressants for Chronic Pain Page(s): 13.

**Decision rationale:** According to the California MTUS Guidelines, antidepressants for chronic pain are recommended as a first-line option for neuropathic pain and are a possibility for non-neuropathic pain. Analgesia generally occurs within a few days to a week, whereas antidepressant effects take longer to occur. Assessment of treatment effectiveness should include not only pain outcomes but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment. It is recommended that these outcome measurements should be initiated at 1 week of treatment with a recommended trial of at least 4 weeks. The clinical information provided for review lacks documentation for the rationale for the request. There is a lack of documentation related to depression and insomnia, or the goal from the use of Somnicin. In addition, the request as submitted failed to provide frequency for the use of Smonicin cap #30. Therefore, the request for Somnicin cap #30 is not medically necessary.