

<b>Case Number:</b>	CM15-0007876		
<b>Date Assigned:</b>	01/26/2015	<b>Date of Injury:</b>	09/16/2011
<b>Decision Date:</b>	03/18/2015	<b>UR Denial Date:</b>	01/08/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/14/2015

### 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: Pennsylvania

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:

This is a 59 year-old female who has reported multifocal pain and mental illness after an injury on 9/16/2011. Painful areas include the low back, right leg, right hip, and right groin. The diagnoses have included articular cartilage disorder, peripheral autonomic neuropathy, osteoarthritis, thoracic lumbosacral neuritis/radiculitis, lumbar sprain/strain; and depressive disorder. Treatments have included multiple consultations, physical therapy, injection therapy; right hip labral surgery (5/13), food supplements, and medications. The work status has remained as temporarily totally disabled. Reports from the primary treating physician (PTP) during 2014 (May-December) document ongoing multifocal pain and dispensing/prescribing of a vast array of food supplements and medications, including those now under Independent Medical Review. None of the reports discuss the patient-specific indications for all these medications and the specific results of using specific medications. Some reports state that unspecified medications provide partial pain relief. Work status in these reports is 'temporarily totally disabled.' Function is not otherwise discussed. Although some reports mention drug testing, no reports describe the specific methodology for any testing or any results of such testing. All the medications now under review have been prescribed chronically, at least for months, although none of the treating physician reports discuss the duration of use and the reasons why the medications should continued chronically. On 1/8/2015 Utilization Review non-certified requests from 1/2/2015 for the oral and topical medications now under Independent Medical Review. The MTUS, the Official Disability Guidelines and Mosby's Drug Consult were cited.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Ambien 10 MG #30:** Upheld

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

**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, insomnia treatment.

**Decision rationale:** The MTUS does not address the use of hypnotics other than benzodiazepines. The Official Disability Guidelines were used instead. No physician reports describe the specific criteria for a sleep disorder. The treating physician has not addressed major issues affecting sleep in this patient, including the use of other psychoactive agents like opioids, which significantly impair sleep architecture, and depression. Zolpidem, a benzodiazepine agonist, is habituating and recommended for short term use only. This injured worker has been given a hypnotic for a duration in excess of what is recommended in the guidelines cited above. This patient has also been given a benzodiazepine, which is additive with the hypnotic, and which increases the risk of side effects and dependency. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. Note the Official Disability Guidelines citation which recommends short term use of zolpidem, a careful analysis of the sleep disorder, and caution against using zolpidem in the elderly. Prescribing in this case meets none of the guideline recommendations. Zolpidem is not medically necessary based on lack of a sufficient analysis of the patient's condition, the Official Disability Guidelines citation, and overuse of habituating and psychoactive medications without clear benefit or indication.

**Oxycodone 20 MG #240:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioid management. Opioids, steps to avoid misuse/addiction indications, Chronic back pain Mec.

**Decision rationale:** There is no evidence that the treating physician is prescribing opioids according to the MTUS, which recommends prescribing according to function, with specific functional goals, return to work, random drug testing, opioid contract, and there should be a prior failure of non-opioid therapy. None of these aspects of prescribing are in evidence. Per the MTUS, opioids are minimally indicated, if at all, for chronic non-specific pain, osteoarthritis, 'mechanical and compressive etiologies,' and chronic back pain. Aberrant use of opioids is common in this population. There is no evidence of significant pain relief or increased function from the opioids used to date. The prescribing physician does not specifically address function with respect to prescribing opioids, and does not address the other recommendations in the

MTUS. The MTUS recommends urine drug screens for patients with poor pain control and to help manage patients at risk of abuse. There is a high rate of aberrant opioid use in patients with chronic back pain. There is no record of a urine drug screen program performed according to quality criteria in the MTUS and other guidelines. The prescribing physician describes this patient as 'temporarily totally disabled,' which fails the 'return-to-work' criterion for opioids in the MTUS, and represents an inadequate focus on functional improvement. Page 60 of the MTUS, cited above, recommends that medications be trialed one at a time. In this case, medications were prescribed together, making the determination of results, side effects, and benefits very difficult to determine. As currently prescribed, oxycodone does not meet the criteria for long term opioids as elaborated in the MTUS and is therefore not medically necessary.

**Xanax 1.0 MG #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

**Decision rationale:** The treating physician has not provided a sufficient account of the indications and functional benefit for this medication. The MTUS does not recommend benzodiazepines for long term use for any condition. Xanax has been dispensed along with potent opioids and Ambien, which is a particularly risky form of prescribing in light of the cumulative toxicity and lack of any clear benefit. Xanax is not prescribed according the MTUS and is not medically necessary.

**Genicin #90:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine Page(s): 50.

**Decision rationale:** The treating physician has not presented or discussed the specific ingredients in this food supplement. Per other sources, Genicin contains some form of glucosamine. The treating physician has not provided clear indications for this supplement in light of the MTUS recommendations. The MTUS recommends glucosamine for arthritis (primarily of the knee), and the glucosamine should be of a specific type defined in the MTUS. The patient does not have a clearly defined arthritis condition per the available reports and there is no evidence of a specific trial of Genicin. Rather, it has been given chronically with no reports of any specific results. There is no evidence of benefit from taking this supplement. The form of glucosamine used in this case may not be the proper form recommended in the MTUS, as the MTUS describes a specific chemical form on which medical evidence is based and the treating

physician has not discussed the nature of the ingredients. Other forms, including food supplements, lack scientific credibility. Genicin is not medically necessary based on the MTUS.

**Somnacin #30:** Upheld

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

**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, insomnia treatment.

**Decision rationale:** The treating physician has not adequately presented or discussed the ingredients of this food supplement. Other sources state that it contains melatonin. The MTUS does not address the use of hypnotics other than benzodiazepines. The Official Disability Guidelines were used instead. No physician reports describe the specific criteria for a sleep disorder. The treating physician has not addressed major issues affecting sleep in this patient, including the use of psychoactive agents like opioids, which significantly impair sleep architecture, and depression. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. There is no evidence of a specific trial of this food supplement, or of any specific benefit. Somnicin is not medically necessary based on the cited guidelines and the lack of any benefit.

**Terocin 120 mL:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain. Topical Analgesics Page(s): 60; 111-113. Decision based on Non- MTUS Citation Other Medical Treatment Guideline or Medical Evidence: December 5, 2006 FDA Alert, FDA Warns Five Firms To Stop Compounding Topical Anesthetic Creams.

**Decision rationale:** The treating physician has not discussed the ingredients of Terocin and the specific indications for this injured worker. Per the manufacturer, Terocin is Methyl Salicylate 25%, Menthol 10%, Capsaicin 0.025%, Lidocaine 2.5%, Aloe, Borage Oil, Boswellia Serrata, and other inactive ingredients. Per page 60 of the MTUS, medications should be trialed one at a time. Regardless of any specific medication indications for this patient, the MTUS recommends against starting 3-7 medications simultaneously. Per the MTUS, any compounded product that contains at least one drug that is not recommended, is not recommended. Boswellia serrata resin and topical lidocaine other than Lidoderm are 'not recommended' per the MTUS. Topical lidocaine in the form of the Lidoderm patch is indicated for neuropathic pain (not present in this case). The MTUS does not recommend Terocin, and does not recommend topical anesthetics other than Lidoderm for neuropathic pain (a condition not present in this case). Note the FDA warning. Topical lidocaine like that in Terocin is not indicated per the FDA, and places patients at an unacceptable risk of seizures, irregular heartbeats and death. Capsaicin alone in the

standard formulation readily available OTC may be indicated for some patients. The indication in this case is unknown, as the patient has not failed adequate trials of other treatments. The treating physician has also prescribed a Terocin patch, which is redundant and possibly toxic. Terocin is not medically necessary based on lack of specific medical indications, the MTUS, lack of medical evidence, FDA directives, and inappropriate prescribing.

**Flurbi (NAP) Cream-LA 180 Grams: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain. Topical Medications Page(s): 60; 111-113.

**Decision rationale:** No physician reports discuss the specific indications and medical evidence in support of the topical medications prescribed in this case. The ingredients appear to include flurbiprofen, amitriptyline, and lidocaine. The treating physician has not discussed the ingredients of this topical agent and the specific indications for this injured worker. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The MTUS states that the only form of topical lidocaine that is recommended is Lidoderm. The topical lidocaine prescribed in this case is not Lidoderm. The treating physician is already prescribing two other forms of Lidocaine, which is toxic and not indicated. Note that topical flurbiprofen is not FDA approved, and is therefore experimental and cannot be presumed as safe and efficacious. Non-FDA approved medications are not medically necessary. There is no good medical evidence for topical antidepressants. The topical agents prescribed are not medically necessary based on the MTUS, lack of medical evidence, FDA directives, and inappropriate prescribing.

**Gabacyclotram 180 Grams: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain. Topical Medications Page(s): 60; 111-113.

**Decision rationale:** No physician reports discuss the specific indications and medical evidence in support of the topical medications prescribed in this case. The ingredients appear to include gabapentin, cyclobenzaprine, and tramadol. The treating physician has not discussed the ingredients of this topical agent and the specific indications for this injured worker. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not

recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Per the MTUS citation, topical gabapentin and muscle relaxants are not recommended. There is no good evidence to support topical opioids (tramadol). The injured worker is already prescribed a potent oral opioid. The topical compounded medication prescribed for this injured worker is not medically necessary based on the MTUS, lack of medical evidence, and lack of any benefit.

**Terocin Pain Patch #20:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain. Topical Analgesics Page(s): 60; 111-113.

**Decision rationale:** The treating physician has not discussed the ingredients of Terocin and the specific indications for this injured worker. Per the manufacturer, Terocin is Methyl Salicylate 25%, Menthol 10%, Capsaicin 0.025%, Lidocaine 2.5%, Aloe, Borage Oil, Boswellia Serrata, and other inactive ingredients. Per page 60 of the MTUS, medications should be trialed one at a time. Regardless of any specific medication indications for this patient, the MTUS recommends against starting 3-7 medications simultaneously. Per the MTUS, any compounded product that contains at least one drug that is not recommended, is not recommended. Boswellia serrata resin and topical lidocaine other than Lidoderm are 'not recommended' per the MTUS. Topical lidocaine in the form of the Lidoderm patch is indicated for neuropathic pain (not present in this case). The MTUS does not recommend Terocin, and does not recommend topical anesthetics other than Lidoderm for neuropathic pain (a condition not present in this case). Note the FDA warning. Topical lidocaine like that in Terocin is not indicated per the FDA, and places patients at an unacceptable risk of seizures, irregular heartbeats and death. Capsaicin alone in the standard formulation readily available OTC may be indicated for some patients. The indication in this case is unknown, as the patient has not failed adequate trials of other treatments. The treating physician has also prescribed a Terocin lotion, which is redundant and possibly toxic. Terocin is not medically necessary based on lack of specific medical indications, the MTUS, lack of medical evidence, FDA directives, and inappropriate prescribing.

**Menthoderm Gel 120 ML:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate topical Page(s): 105.

**Decision rationale:** Per the MTUS, there may an indication for topical salicylates to treat chronic pain. The treating physician has not discussed the ingredients of this topical agent and

the specific indications for this injured worker. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. A specific trial of Methoderm was not performed. Rather, it was dispensed along with many other medications. There is no evidence of any specific symptomatic and functional benefit. Methoderm is not medically necessary as there is a lack of evidence for specific benefit and prescribing was not in accordance with the MTUS.