

<b>Case Number:</b>	CM14-0092098		
<b>Date Assigned:</b>	08/04/2014	<b>Date of Injury:</b>	06/20/2012
<b>Decision Date:</b>	09/12/2014	<b>UR Denial Date:</b>	05/29/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/18/2014

### 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 Pain Medicine and Rehabilitation, has a subspecialty in Interventional Spine and is licensed to practice in California. 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 53 year old female with an injury date on 06/20/2012. Based on the 04/11/2014 progress report provided by [REDACTED], the diagnoses are: 1. Lumbar Radiculopathy. 2. Lumbar Spinal Stenosis, 3. Lumbar Spondylitis, 4. Lumbar Disc Protrusion, 5. Diabetes. According to this report, the patient complains of constant low back pain radiating to the lower extremities with numbness and tingling, 8/10. Patient denies any side effects to current medications. Pain without medication is 10/10 reduced to 7-10 while taking medications. Creams and patches decrease pain, increase sleep and allow the patient to walk longer. Lumbar range of motion: flexion 30; extension 10; rt. lateral flexion 10; lt. lateral flexion 10. Straight Leg Raising (SLR) is positive, bilaterally. Tenderness and spasms are noted at the lumbar spine. There were no other significant findings noted on this report. [REDACTED] is requesting: 1. Valium 5 mg #2. 2. Topical: Flurbi(nap) Cream - LA 180grms. 3. Gabacyclotram 180 gms. 4. Somnicin #30. 5. Terocin 240ML. 6. Capsaicin .0025 %. 7. Terocin Patches #20. 8. Methoderm Gel #240. 9. Xollndo 2 % Cream. 10. Genecin 90 Capsules. The utilization on review denied the request on 05/29/2014. [REDACTED] is the requesting provider, and he provided treatment reports from 01/17/2013 to 04/25/2014.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Valium 5 mg #2:** 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.

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

**Decision rationale:** According to the 04/11/2014 report by [REDACTED] this patient presents with constant low back pain radiating to the lower extremities with numbness and tingling. The treating physician is requesting Valium 5mg #2. Valium was first noted on the 01/23/2014 report. The MTUS guidelines state that "Benzodiazepines are not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence." Most guidelines limit use to 4 weeks. The patient has been utilizing Valium for at least 3 months which is not supported by MTUS. Recommendation is not medically necessary.

**Topical: Flurbi(nap) Cream - LA 180grms: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** According to the 04/11/2014 report by [REDACTED] this patient presents with constant low back pain radiating to the lower extremities with numbness and tingling. The treating physician is requesting Flurbi(nap) Cream - LA 180grms. Regarding topical NSAIDS, MTUS guidelines recommends for Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment. In this case, the patient does not meet the indication for the topical medication as she does not present with any osteoarthritis or tendonitis symptoms. In addition, Lidocaine is only allowed in a patch form and not allowed in cream, lotion or gel forms. The MTUS Guidelines page 111 has the following regarding topical creams, "topical analgesics are largely experimental and used with few randomized control trials to determine efficacy or safety." MTUS further states, "any compounded product that contains at least one (or drug class) that is not recommended is not recommended." Recommendation is not medically necessary.

**Gabacyclotram 180 gms: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical creams Page(s): 111.

**Decision rationale:** According to the 04/11/2014 report by [REDACTED] this patient presents with constant low back pain radiating to the lower extremities with numbness and tingling. The

treating physician is requesting Gabacyclotram 180 gms. The MTUS Guidelines regarding topical analgesics states "that it is largely experimental in use with few randomized controlled trials to determine efficacy or safety." MTUS further states, "any compounded product that contains at least one (or drug class) that is not recommended is not recommended." Cyclobenzaprine is a muscle relaxant and is not recommended for any topical formulation. Furthermore, Gabapentin is not recommended as a topical formulation. Recommendation is not medically necessary.

### **Somnicin #30:** 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).

**Decision rationale:** According to the 04/11/2014 report by [REDACTED] this patient presents with constant low back pain radiating to the lower extremities with numbness and tingling. The treater is requesting Somnicin #30. The MTUS, ACOEM and ODG guidelines do not discuss Somnicin. The search on the web indicates Somnicin is an oral medication of natural ingredients, helps and promotes sleep. Active Ingredients are Melatonin 2 mg, 5-HTP (5-hydroxytrptopan) 50 mg, L-tryptophan 100 mg, Vitamin B6 (pyridoxine) 10 mg, Magnesium 50 mg. (<http://sales.advancedrxmgt.com/salescontent/uploads/2012/04/Somnicin-Patient-Info-Sheet.pdf>). Somnicin is a supplement and it is not Food and Drug Administration (FDA) approved to treat any medical condition and cannot be considered a medical treatment for any condition. Official Disability Guidelines (ODG) do address some of these items separatel, however they do not recommend meltonin-receptor agonist for more than 7-10 days, and do not recommend Vitamin B supplements. ODG guidelines do recommend 5-hydroxytryptophan is recommended to be use with caution. Given that some of the ingredients lack guidelines support, recommendation is not medically necessary.

### **Terocin 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): 111-113.

**Decision rationale:** According to the 04/11/2014 report by [REDACTED] this patient presents with constant low back pain radiating to the lower extremities with numbness and tingling. The treating physician is requesting Terocin 240ML. Regarding topical lidocaine, MTUS guidelines states, "recommended 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)." Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the Food and Drug Administration (FDA) for neuropathic pain. Lidoderm is

also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. MTUS further states, "any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." For salicylate, a topical NSAID, MTUS does allow it for peripheral joint arthritis/tendinitis problems. However, the patient does not present with peripheral joint problems to warrant a compound product with salicylate. Furthermore, the MTUS guidelines do not allow any formulation of Lidocaine other than in patch form. Therefore, it is not medically necessary.

**Capsaicin .0025 %:** Overturned

**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 04/11/2014 report by [REDACTED] this patient presents with constant low back pain radiating to the lower extremities with numbness and tingling. The treating physician is requesting Capsaicin 0.025%. MTUS supports use of capsaicin for non-specific chronic low back pain (p29). This patient presents with chronic low back pain and recommendation is medically necessary.

**Terocin Patches #20:** 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): 56-57, 111-113.

**Decision rationale:** According to the 04/11/2014 report by [REDACTED] this patient presents with constant low back pain radiating to the lower extremities with numbness and tingling. The treating physician is requesting Terocin Patches #20. Terocin patches are a dermal patch with 4% lidocaine, and 4% menthol. Terocin patch was first noted in the 01/23/2014 report. The MTUS guidelines state that "Lidoderm patches may be recommended for neuropathic pain when trials of antidepressants and anti-convulsants have failed." Review of the reports indicate that the patient has numbness and tingling of the lower extremities indicated for neuropathic pain. However, there is no documentation of the effects of this medication as required per page 60 of MTUS. Furthermore, Lidoderm patches are not recommended for axial back pain but peripheral, localized neuropathic pain. Recommendation is not medically necessary.

**Methoderm Gel #240:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** According to the 04/11/2014 report by [REDACTED] this patient presents with constant low back pain radiating to the lower extremities with numbness and tingling. The treating physician is requesting Methoderm gel #240. Regarding Topical Lidocaine, MTUS guidelines states, "recommended 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)." Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the Food and Drug Administration (FDA) for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. MTUS further states, "any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." For salicylate, a topical NSAID, MTUS does allow it for peripheral joint arthritis/tendinitis problems. However, the patient does not present with peripheral joint problems to warrant a compound product with salicylate. Furthermore, the MTUS guidelines do not allow any formulation of Lidocaine other than in patch form. Therefore, recommendation is not medically necessary.

**Xolido 2 % Cream:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** According to the 04/11/2014 report by [REDACTED] this patient presents with constant low back pain radiating to the lower extremities with numbness and tingling. The treating physician is requesting Xolido 2 % Cream. Xolido is a topical lidocaine cream. Lidocaine is only allowed in a patch form and not allowed in cream, lotion or gel forms. The MTUS Guidelines page 111 has the following regarding topical creams, "topical analgesics are largely experimental and used with few randomized control trials to determine efficacy or safety." Recommendation is not medically necessary.

**Genecin 90 Capsules:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Glucosamine Chondroitin Arthritis Intervention Trial (Distler 2006).

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

**Decision rationale:** According to the 04/11/2014 report by [REDACTED] this patient presents with constant low back pain radiating to the lower extremities with numbness and tingling. The treating physician is requesting Genecin # 90 Capsules. Regarding Glucosamine, MTUS guidelines state "recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis." In this case, the patient does not meet the indication for Glucosamine, as she does not present with knee osteoarthritis. Per MTUS guidelines, recommendation is not medically necessary.