

<b>Case Number:</b>	CM14-0076273		
<b>Date Assigned:</b>	08/06/2014	<b>Date of Injury:</b>	05/10/2012
<b>Decision Date:</b>	09/17/2014	<b>UR Denial Date:</b>	04/30/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/26/2014

### 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 & Rehabilitation, 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 injured worker is a 56-year-old male who reported an injury on 05/10/2012. The mechanism of injury was the injured worker was disassembling a fender, when the door which was in an open position suddenly closed due to a gust of wind. The injured worker's medication history included Terocin, Flurbiprofen (NAP) cream, Gabacyclotram, Genecin, and Somnicin as of at least 09/18/2013. The injured worker was noted to undergo urine drug screens. The injured worker was noted to be utilizing Methoderm since at least 08/07/2013. The documentation that was closest to the requested date of service was dated 02/18/2014. The injured worker was noted to have bilateral shoulder pain and frequency wrist pain with numbness and tingling. The pain without medications was an 8/10 and with medications a 5/10 - 6/10. The topical medications were noted to increase sleep, decrease pain, and the injured worker was able to walk and sit longer. The objective findings revealed the injured worker had decreased range of motion of the bilateral shoulders. The injured worker had impingement and supraspinatus testing that was positive bilaterally. The injured worker had tender AC joints. The injured worker had a positive Phalen's bilaterally. The left upper extremity had sensation that was decreased at C6-8. The diagnoses include bilateral shoulder sprain and strain, left shoulder tendinitis, bilateral carpal tunnel syndrome, left knee medial meniscus tear, chondromalacia of patella, and ACL tear. The treatment plan included a urine drug screen, transportation to and from all office visits, Methoderm gel #240, Terocin 120 mL, Flurbi nap cream LA 180 g, Gabacyclotram 180 mg, Genecin, and Somnicin #30. There was no request made for the other medications. The medications requested were noted to include Theramine, Sentra AM and PM, GABAdone, Genecin, Gabacyclotram, Terocin, Somnicin, Flurbiprofen, and Methoderm. There was a Request for Authorization submitted for GABAdone #60, Sentra AM #60, Sentra PM #60 and Theramine #90 on 01/16/2014.

## IMR ISSUES, DECISIONS AND RATIONALES

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

### **Retrospective request for Theramine, qty 90, DOS 01/14/14: 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 (ODG) Pain Chapter, Theramine®.

**Decision rationale:** The documentation indicated the injured worker had been utilizing Genecin, Gabacyclotram, Terocin, Somnicin and Flurbi nap since at least 09/2013. The injured worker was utilizing Menthoderm since at least 08/2013. The Official Disability Guidelines do not recommend Theramine. The clinical documentation submitted for review failed to provide a rationale for the requested medication. There was no documented rationale for the requested medication. There was a lack of documentation indicating the efficacy for the requested medication and the duration of use could not be established. There was no PR2 submitted for the requested date of service. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the retrospective request for Theramine quantity 90, date of service 01/14/2014, is not medically necessary.

### **Retrospective request for Somnicin, qty 30, DOS 01/14/14: 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 (ODG) Pain Chapter, Insomnia Treatment/Other Medical Treatment Guideline or Medical Evidence: <http://sales.advancedrxmgt.com/sales-content/uploads/2012/04/Somnicin-Patient-Info-Sheet.pdf>.

**Decision rationale:** The Official Disability Guidelines indicates that non-pharmacologic treatment includes stimulus control, progressive muscle relaxation, and paradoxical intention. Treatments that are thought to probably be efficacious include sleep restriction, biofeedback, and multifaceted cognitive behavioral therapy. Suggestions for improved sleep hygiene: (a) Wake at the same time every day; (b) Maintain a consistent bedtime; (c) Exercise regularly (not within 2 to 4 hours of bedtime); (d) Perform relaxing activities before bedtime; (e) Keep your bedroom quiet and cool; (f) Do not watch the clock; (g) Avoid caffeine and nicotine for at least six hours before bed; (h) Only drink in moderation; & (i) Avoid napping. Per advancedrxmgt.com, "Somnicin, an oral medication of natural ingredients, helps and promotes sleep. Insomnia and sleeping problems can be linked to pain and often thought of as a sign and/or symptom of physical, emotional, and/or mental health. Somnicin's ingredients help relax the body, allow adequate blood flow, and may help in other conditions such as depression, anxiety, or some pains. Melatonin, 5-HTP, and L-tryptophan, help balance the pathway responsible for a normal

sleep cycle". Also included in the compound are B-6 and Magnesium. The clinical documentation submitted for review indicated the injured worker had utilized the medication since at least 09/2013. The request as submitted failed to indicate the frequency for the requested medication. There was a lack of documentation indicating the efficacy for the requested medication and the duration of use could not be established. There was no PR2 submitted for the requested date of service. Given the above, the retrospective request for Somnicin quantity 30, date of service 01/14/2014, is medically necessary.

**mentoderm Gel, qty 240ml: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Topical Salicylates Page(s): 111, 105.

**Decision rationale:** The California MTUS guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. They further indicate that topical salicylates are appropriate for the treatment of pain. The clinical documentation submitted for review indicated the injured worker had utilized the medication since at least 08/2013. There was a lack of documented objective functional benefit. There was a lack of documentation indicating antidepressants and anticonvulsants had failed. There was no PR-2 submitted for the request date of service. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Methoderm gel quantity 240 mL is not medically necessary.

**Retrospective request for Sentra AM, qty 60, DOS 01/14/14: 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 (ODG), Pain Chapter, Medical Foods.

**Decision rationale:** Per Marvista health center.com Sentra AM is a blend of Choline bitartrate and glutamate, acetyl-L-carnitine, cocoa powder, ginkgo biloba and grape seed extract and is utilized in the treatment of chronic and generalized fatigue, fibromyalgia, post-traumatic stress disorder. Per Official Disability Guidelines, to be considered the product must be a food for oral or tube feeding, must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements and the product must be used under medical supervision. The clinical documentation submitted for review failed to document the above criteria per the Official Disability Guidelines. There was a lack of documentation of exceptional factors toward non-adherence to guideline recommendations. The duration of use could not be established. The specific PR2 was not supplied for the requested date of service.

Given the above, the retrospective request for Sentra AM, quantity 60, date of service 01/14/2014, is not medically necessary.

**Retrospective request for Sentra PM, qty 60, DOS 01/14/14: 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 (ODG) Pain Chapter, Sentra PM.

**Decision rationale:** The Official Disability Guidelines indicates that Sentra PM and is intended for use in management of sleep disorders associated with depression. It is a blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. Glutamic Acid is used in complementary medicine for digestive disorders. 5-hydroxytryptophan is possibly effective in treatment of anxiety disorders, fibromyalgia, obesity and sleep disorders. The clinical documentation submitted for review failed to provide a documented rationale for the use of the medication. There was a lack of documentation of a PR2 for the requested date of service. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the retrospective request for Sentra PM, quantity 60, date of service 01/14/2014, is not medically necessary.

**Retrospective request for Gabadone, qty 60, DOS 01/14/14: 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 (ODG) Pain Chapter, Gabadone.

**Decision rationale:** The Official Disability Guidelines do not recommend GABAdone. The duration of use was not provided. The clinical documentation submitted for review indicated the injured worker had utilized the medication since at least 09/2013. The request as submitted failed to indicate the frequency for the requested medication. There was a lack of documentation indicating the efficacy for the requested medication. There was no PR2 submitted for the requested date of service. Given the above, the retrospective request for GABAdone, quantity 60, date of service 01/14/2014, is not medically necessary.

**Terocin, qty 240ml: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals, Topical Analgesic, Topical Capsaicin, Lidocaine Page(s): 105, 111, 28, 112. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence:<http://www.drugs.com/search.php?searchterm=Terocin>.

**Decision rationale:** The California MTUS guidelines indicate that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety... are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed...Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended...Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. The guidelines indicate that topical Lidocaine (Lidoderm) may be 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). ...No other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. The guidelines recommend treatment with topical salicylates. Per Drugs.com, Terocin is a topical analgesic containing Capsaicin / Lidocaine / menthol / methyl salicylate. The clinical documentation submitted for review failed to provide documentation the injured worker had a trial and failure of antidepressants and anticonvulsants. There was documentation the injured worker had utilized the medication since at least 09/2013. There was a lack of documented efficacy. The request as submitted failed to indicate the frequency and the body part to be treated with the Terocin. Given the above, the request for Terocin, quantity of 240 ml, is not medically necessary.

**Flurbi (NAP) Cream, qty 180gm:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen, page 72, Topical analgesics page 111, Lidocaine page 112, Antidepressants, page 13 Page(s): 72, 111, 112, 13. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Skolnick P (1999) Antidepressants for the new millennium. Eur J Pharmacol 375:31-40.

**Decision rationale:** The California MTUS indicates topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed....Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Flurbiprofen is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institute of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration. The guidelines indicate that topical Lidocaine (Lidoderm) may be 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). No other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Per Skolnick, P. (1999) "while local peripheral administration of antidepressants has been demonstrated to produce analgesia in the formalin model of tonic pain; a number of actions, to include inhibition of noradrenaline (NA) and 5-HT reuptake, inhibition of NMDA, nicotinic, histamine, and 5-HT receptors, and block of ion channels and even combinations of these actions, may contribute to the local peripheral efficacy of antidepressant; therefore the contribution of these actions to analgesia by antidepressants, following either systemic or local administration, remains to be determined". Additionally, there was a lack of documentation indicating a necessity for 2 topical creams containing Lidocaine. The clinical documentation submitted for review failed to indicate the injured worker had a trial and failure of antidepressants and anticonvulsants. The documentation indicated the injured worker had utilized the medication since at least 09/2013. There was a lack of documented efficacy including objective functional improvement. The request as submitted failed to indicate the frequency for the requested medication. There was no PR2 submitted for the requested date of service. Additionally, there was a lack of documentation for the submitted request for the frequency and the body part to be treated with the medication. Given the above, the request for Flurbi nap cream, quantity 180 g, is not medically necessary.

**Gabacyclotram, qty 180gm: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Topical Analgesics, Gabapentin, Tramadol Page(s): 41, 111, 113, 82. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: FDA.gov.

**Decision rationale:** The California MTUS guidelines indicate that that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety... are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed...Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended...Gabapentin is not recommended. There is no peer-reviewed literature to support use. Other anti-epilepsy drugs: There is no evidence for use of any other anti-epilepsy drug as a topical product...do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product...The addition of cyclobenzaprine to other agents is not recommended. A thorough search of FDA.gov, did not indicate there was a formulation of topical Tramadol that had been FDA approved. The approved form of Tramadol is for oral consumption, which is not recommended as a first line therapy per CA MTUS guidelines. The clinical documentation submitted for review indicated the injured worker had utilized the medication since at least 09/2013. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. There was a lack of documented efficacy. The request as submitted failed to indicate the frequency for the requested medication. There was

no DWC form RFA submitted for the requested medication. Given the above, the request for Gabapenclotram, quantity 180 g, is not medically necessary. The request as submitted failed to indicate the frequency and body part to be treated.

**Retrospective request for Genicin 500mg, qty 90, DOS 01/14/14: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** The California MTUS Guidelines recommend Tramadol for pain; however, do not recommend it as a first-line oral analgesic and they recommends Glucosamine Sulfate for patients with moderate arthritis pain especially, knee osteoarthritis. The clinical documentation submitted for review failed to indicate the injured worker had osteoarthritis. The request as submitted failed to indicate the frequency for the requested medication. The documentation indicated the injured worker had utilized the medication since at least 09/2013. There was no PR2 submitted for the requested date of service, 01/14/2014. Given the above, the retrospective request for Genecin 500 mg, quantity 90, date of service 01/14/2014, is not medically necessary.

**Retrospective request for Urine Drug Screen, qty 1, DOS 01/14/14: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Ongoing Management Page(s): 78.

**Decision rationale:** The California MTUS Guidelines recommend urine drug screens for injured workers who have documented issues of addiction, abuse, or poor pain control. The clinical documentation submitted for review failed to indicate the injured worker was utilizing a medication that would necessitate a urine drug screen. There was a lack of documentation of the above criteria. The documentation indicated the injured worker had previously undergone urine drug screens. There was no DWC form RFA submitted for the requested urine drug screen. Given the above, the retrospective request for Urine Drug Screen, quantity 1, date of service 01/14/2014, is not medically necessary.

**Retrospective request for Pain Management Follow-up, DOS 02/17/14: 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 (ODG) Pain Chapter, Office Visit.

**Decision rationale:** The Official Disability Guidelines recommend office visits based upon the review of the injured worker's concerns, signs and symptoms, clinical stability and reasonable physician judgment. Additionally, the office visits are based on what medications the injured worker is taking such as opiates. The clinical documentation submitted for review failed to indicate the injured worker was taking medications that would require return visits with a pain management specialist. There was a lack of documented rationale. There was no Request for Authorization submitted for the request or PR2 submitted for the requested date of service, 02/17/2014. There was a lack of documented rationale. Given the above, the retrospective request for pain management follow-up, date of service 02/17/2014, is not medically necessary.