

<b>Case Number:</b>	CM14-0089928		
<b>Date Assigned:</b>	07/30/2014	<b>Date of Injury:</b>	01/28/2002
<b>Decision Date:</b>	10/07/2014	<b>UR Denial Date:</b>	06/05/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/13/2014

### 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 Internal Medicine 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 58 year old male who was injured on 01/20/2002. The patient underwent ankle fusion on 08/07/2009 which is his 4th surgery in 7 years. Prior treatment history has included TENS unit which gives him temporary relief. Progress report dated 05/27/2014 documented the patient to have complaints left ankle pain due to over compensation, and reported right leg pain. He has had surgery for the ankle but continues with the pain. His pain becomes worse when he weightbears and reported he swims regularly for exercise. He rated his pain with his medications a 6-7/10 and without medications a 10/10. On exam, weightbearing is 45%. He is unable to flex and extend ankle to more than 15 degrees; 10 degrees with medial and lateral range of motion of the ankle. He is wearing ortho shoes, brace and crutches in place. He is diagnosed with left ankle derangement; right wrist strain; ambulation dysfunction; long-term use of medications and encounter for therapeutic drug monitoring. The recommendation is to have the patient continue to see [REDACTED] for his foot. His medications were refilled which included Paxil, Theramine, Sentra PM, Sentra AM, trepadone. The use of Sprix was discussed to decrease his use of OxyContin. Prior utilization review dated 06/05/2014 states the request for Trepadone, Qty 60 is denied as medical necessity has not been established; and Theramine Qty 90; Sentra Pm, Qty 60 Sprix Nasal Spray; And Sentra Am, Qty 60 are denied as they are not considered medically necessary.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**SENTRA AM, Qty 60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disabilities 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, Medical Food X Other Medical Treatment Guideline or Medical Evidence:  
[http://nutrientpharmacology.com/sentra\\_AM.html](http://nutrientpharmacology.com/sentra_AM.html)

**Decision rationale:** CA MTUS guidelines are silent regarding the Sentra AM. This medication is a medical food with multiple components. Some of the components have no validated medical use. The guidelines state that any compounded medication that contains at least one compound which is not recommended renders the entire product to be not recommended. This substance contains choline which has no validated medical use in the current literature. The clinical documents did not provide sufficient information to certify this medication outside of current guidelines. Based on the guidelines and criteria as well as the clinical documentation stated above, the request is not medically necessary.

**SENTRA PM, Qty 60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disabilities 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, Medical Food Other Medical Treatment Guideline or Medical Evidence:  
<http://nutrientpharmacology.com/PDFs/monographs/sentraPM-monograph.pdf>

**Decision rationale:** CA MTUS guidelines are silent regarding the Sentra PM. This medication is a medical food with multiple components. Some of the components have no validated medical use. The guidelines state that any compounded medication that contains at least one compound which is not recommended renders the entire product to be not recommended. This substance contains choline which has no validated medical use in the current literature. The clinical documents did not provide sufficient information to certify this medication outside of current guidelines. Based on the guidelines and criteria as well as the clinical documentation stated above, the request is not medically necessary.

**SPRIX NASAL SPRAY:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-73. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: <http://www.sprix.com/Home.aspx>

**Decision rationale:** The guidelines recommend Sprix for short-term management of moderate to severe pain. The duration of the use of the medication should not exceed 5 days. The request did not indicate the frequency or duration of the requested medication. The medical documents did not justify the use of the medication which fit within the current guidelines. The documents did not provide details about dosing, frequency, and duration of therapy. Based on the guidelines and criteria as well as the clinical documentation stated above, the request is not medically necessary.

**TREPADONE, Qty 60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disabilities 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, Medical Food X Other Medical Treatment Guideline or Medical Evidence:  
<http://nutrientpharmacology.com/PDFs/monographs/trepadone-monograph.pdf>

**Decision rationale:** CA MTUS guidelines are silent regarding the Trepadone. This medication is a medical food with multiple components. Some of the components have no validated medical use. The guidelines state that any compounded medication which contains at least one compound which is not recommended renders the entire product to be not recommended. This substance contains choline and L-serine both have which have no validated medical use in the current literature. The clinical documents did not provide sufficient information to certify this medication outside of current guidelines. Based on the guidelines and criteria as well as the clinical documentation stated above, the request is not medically necessary.

**Theramine Qty 90:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation X Official Disability Guidelines (ODG), Pain, Medical Food X Other Medical Treatment Guideline or Medical Evidence:  
<http://nutrientpharmacology.com/theramine.html>

**Decision rationale:** CA MTUS guidelines are silent regarding the Theramine. This medication is a medical food with multiple components. Some of the components have no validated medical use. The guidelines state that any compounded medication which contains at least one compound which is not recommended renders the entire product to be not recommended. This substance contains choline and L-serine both have which have no validated medical use in the current literature. The clinical documents did not provide sufficient information to certify this medication outside of current guidelines. Based on the guidelines and criteria as well as the clinical documentation stated above, the request is not medically necessary.