

<b>Case Number:</b>	CM14-0035120		
<b>Date Assigned:</b>	06/23/2014	<b>Date of Injury:</b>	01/22/1999
<b>Decision Date:</b>	09/12/2014	<b>UR Denial Date:</b>	03/05/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/21/2014

### 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:

According to the records made available for review, this is a 54-year-old male with a 1/22/99 date of injury. At the time (3/5/14) of the Decision for Prazolamine NCD and Theraprogen 800 NDC, there is documentation of subjective (neck pain and shoulder/upper pain) and objective (decreased range of motion of the cervical spine with paravertebral tenderness and spasms, and decreased right shoulder range of motion with positive impingement sign) findings, current diagnoses (cervical sprain, cervical spondylosis without myelopathy, and chronic pain syndrome versus fibromyalgia), and treatment to date (not specified).

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Prazolamine NCD:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines on Compounded Drugs.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Theramine; Medical food Other Medical Treatment Guideline or Medical Evidence: (<http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=99265e39-af23-43eb-a552-305f0a218fdf>).

**Decision rationale:** An online search identifies that Prazolamine NCD is a medical food consisting of Carisoprodol and Theramine; that this drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. MTUS does not address the issue. ODG identifies that Theramine is a medical food and is not recommended. In addition, ODG identifies that 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 must be used under medical supervision; as criteria to support the medical necessity of medical food. Within the medical information available for review, there is documentation of diagnoses of cervical sprain, cervical spondylosis without myelopathy, and chronic pain syndrome versus fibromyalgia. However, there is no documentation that the product is labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements. Therefore, based on guidelines and a review of the evidence, the request for Prazolamine NCD is not medically necessary.

**Theraprogen 800 NDC:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Non-steroidal Anti-inflammatory Drugs.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Theramine; Medical food Other Medical Treatment Guideline or Medical Evidence: (<http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=08570dbd-45f7-47d2-8b63-b4e63995e966>).

**Decision rationale:** An online search identifies that Theraprogen 800 NDC is a medical food consisting of Ibuprofen and Theramine; that this drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. MTUS does not address the issue. ODG identifies that Theramine is a medical food and is not recommended. In addition, ODG identifies that 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 must be used under medical supervision; as criteria to support the medical necessity of medical food. Within the medical information available for review, there is documentation of diagnoses of cervical sprain, cervical spondylosis without myelopathy, and chronic pain syndrome versus fibromyalgia. However, there is no documentation that the product is labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements. Therefore, based on guidelines and a review of the evidence, the request for Theraprogen 800 NDC is not medically necessary.