

<b>Case Number:</b>	CM15-0144421		
<b>Date Assigned:</b>	08/05/2015	<b>Date of Injury:</b>	03/06/2009
<b>Decision Date:</b>	09/01/2015	<b>UR Denial Date:</b>	06/26/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/24/2015

### 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: New Jersey, Alabama, California  
 Certification(s)/Specialty: Neurology, Neuromuscular 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:

The injured worker (IW) is a 56-year-old male who sustained an industrial injury on 3-06-2009. Diagnoses include chronic pain syndrome; lumbar back pain; cervical and lumbar sprain and strain; long-term (current) use of medications; lumbar disc herniation with radiculitis; and cervical radiculopathy. Treatment to date has included medications, activity modification and epidural steroid injection (ESI). According to the progress notes dated 6-16-2015, the IW reported continued upper back pain, for which the Norco and compounded cream are effective. The pain was described as going up the back with stabbing and burning; he rated it 6 out of 10. He also complained of intermittent bilateral hand numbness. The IW was going to the gym three times a week for strengthening, but focused instead on flexibility when his symptoms worsened. He rated his pain 9 out of 10 without medications and 4 to 5 out of 10 with medications. On examination, there was tenderness and spasms bilaterally in the cervical and lumbar paraspinals and trapezius muscles, with decreased range of motion. Reflexes were within normal limits; sensation was decreased bilaterally. The lumbar spine MRI dated 2-5-2014 showed disc desiccation and disc bulges measuring 1.5 mm at L3-4 through L5-S1. A request was made Theramine capsules, #90 (22 day supply) to reduce the need for Norco (although the notes stated Theramine would be discontinued due to ineffectiveness); Miseflex-C tablets, #90 (30 day supply) with three refills; and compounded topical cream: Flurbiprofen-Ultraderm, #60 (30 day supply).

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Theramine capsules, #90 (22 day supply): 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-Teramine.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medical Food.  
<http://worklossdatainstitute.verioiponly.com/odgtwc/pain.htm#Medicalfood>.

**Decision rationale:** According to ODG guidelines, medical food. "Recommended as indicated below. Definition: Defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as a food which is formulated to be consumed or administered entirely under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation". There are no controlled studies supporting the safety and efficacy for the use of Theramine for the treatment of pain. Furthermore, there is no documentation that the patient suffered from a nutrition deficit that requires the use of Theramine. Based on the above, the prescription of Theramine capsules, #90 (22 day supply) is not medically necessary.

**Miseflex-C tablets, #90 (30 day supply) with 3 refills: 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 - Medical food.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medical Food.  
<http://worklossdatainstitute.verioiponly.com/odgtwc/pain.htm#Medicalfood>.

**Decision rationale:** According to ODG guidelines, medical food. "Recommended as indicated below. Definition: Defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as a food which is formulated to be consumed or administered entirely under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." There are no controlled studies supporting the safety and efficacy for the use of Miseflex-C for the treatment of pain. Furthermore, there is no documentation that the patient suffered from a nutrition deficit that requires the use of Miseflex-C. Based on the above, the prescription of Miseflex-C tablets, #90 (30 day supply) with 3 refills is not medically necessary.

**Compounded topical cream: Flurbipro/Ultraderm, #60 (30 day supply): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

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

**Decision rationale:** According to MTUS, in Chronic Pain Medical Treatment guidelines section Topical Analgesics (page 111), topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Many agents are combined to other pain medications for pain control. There is limited research to support the use of many of these agents. Furthermore, according to MTUS guidelines, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. There is no documentation that all components of the prescribed topical analgesic are effective for the treatment of chronic pain. There is no documentation of failure or intolerance of first line oral medications for the treatment of chronic pain in this case. Therefore, Compounded topical cream: Flurbipro/Ultraderm, #60 (30 day supply) is not medically necessary.