

<b>Case Number:</b>	CM15-0027767		
<b>Date Assigned:</b>	02/20/2015	<b>Date of Injury:</b>	05/13/2013
<b>Decision Date:</b>	04/03/2015	<b>UR Denial Date:</b>	01/20/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/13/2015

### 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: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

### 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 55 year old female, who sustained an industrial injury on May 13, 2013. The diagnoses have included abdominal pain, acid reflux rule out ulcer/anatomical alteration, constipation, orthopedic diagnosis, psychiatric diagnosis and sleep disorder. Currently, the injured worker complains of abdominal pain and constipation. In a progress note dated January 6, 2015, the treating provider reports no significant findings. On January 20, 2015 Utilization Review non-certified a Sentra PM quantity 60 two refills, Sentra AM quantity 60 with two refills, and Linzess 145mcg daily quantity 30, noting, Official Disability Guidelines and <http://ncbi.nlm.nih.gov/pmc/articles/PMC3638410/> was cited.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Sentra PM #60 with 2 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.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disability guidelines pain chapter regarding Medical Food.

**Decision rationale:** This patient presents with abdominal pain, acid reflux, constipation and difficulties with sleep. The current request is for SENTRA PM #60 WITH 2 REFILLS. The ODG guidelines under the pain chapter regarding Medical Food states that, "Sentra PM" is a medical food from [REDACTED], [REDACTED], intended for use in management of sleep disorders associated with depression, that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. ODG further states that for choline, "There is no known medical need for choline supplementation". For Glutamic Acid, "This supplement is used for treatment of hypochlohydria and achlorhydria. Treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. It is generally used for digestive disorders in complementary medicine". For 5-hydroxytryptophan, "This supplement has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity and sleep disorders. It has been found to be effective for depression". In this case the treating physician has prescribed a compounded medical food and only one component of Sentra PM is recommended for the treatment of sleep disorder. The other ingredients listed for Sentra PM, Choline and Glutamic acid are not supported and the treating physician has not provided any medical rationale to prescribe a medical food that contains ingredients not supported by the ODG guidelines. This request IS NOT medically necessary.

**Sentra AM #60 with 2 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.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://tmedpharma.com/docs/Medical-Foods-by-issacson.pdf> Official disability guidelines pain chapter regarding Medical Food.

**Decision rationale:** This patient presents with abdominal pain, acid reflux, constipation and difficulties with sleep. The current request is for SENTRA AM #60 WITH 2 REFILLS. As per a document published at <http://tmedpharma.com/docs/Medical-Foods-by-issacson.pdf>, "Sentra AM is purely a cholinergic modulator, providing supplementation in choline and acetylcarnitine which are both acetylcholine precursors. Its claims include the ability to increase amounts of acetylcholine at the molecular level. Small double-blinded trials with emphasis on imaging data conducted by the manufacturer have demonstrated increased choline in the CNS of treated patients versus selected subjects. The indication thus spans entities as variable as fibromyalgia, sleep/arousal dysregulation syndromes and cognitive decline". The MTUS and ACOEM guidelines are silent when it comes to this product. The ODG guidelines under the pain chapter regarding Medical Food states that for Choline, "There is no known medical need for choline supplementation." In this case, choline an ingredient in Sentra is not supported by ODG guidelines and the treating physician has not provided any medical rationale to prescribe a medical food that contains an ingredient that is not supported by the ODG guidelines. This request IS NOT medically necessary.

**Linzess 145mcg #30:** Overturned

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation [www.ncbi.nlm.nih.gov](http://www.ncbi.nlm.nih.gov).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Therapeutic Trial of Opioids Page(s): 77.

**Decision rationale:** This patient presents with abdominal pain, acid reflux, constipation and difficulties with sleep. The current request is for LINZESS 145MCG #30. MTUS Chronic Pain Medical Treatment Guidelines, page 77 under the heading: Therapeutic Trial of Opioids, Initiating Therapy states that when initiating a trial of opioids, that "Prophylactic treatment of constipation should be initiated." In this case, the patient reports that her chronic constipation has improved since starting Linzess. The use of Linzess is in accordance with the MTUS guidelines. The request for Linzess IS medically necessary.