

<b>Case Number:</b>	CM15-0124664		
<b>Date Assigned:</b>	07/09/2015	<b>Date of Injury:</b>	03/16/2012
<b>Decision Date:</b>	08/11/2015	<b>UR Denial Date:</b>	06/15/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/29/2015

### 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: Family Practice

### 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 60 year old male who sustained an industrial injury on 03/18/12. Initial complaints and diagnoses are not available. Treatments to date include lumbar fusion and medications. Diagnostic studies are not addressed. Current complaints include low back pain radiating to the lower extremities. Current diagnoses include lumbar facet syndrome. In a progress note dated 05/07/15 the treating provider reports the plan of care as a TENS unit trial, home exercise program, a MRI of the lumbar spine, a heating pad and a lumbar spine brace, medications including Norco, cyclobenzaprine, and Terocin pain Patches, and a compound of Terocin/capsaicin/methyl Salicylate/menthol/lidocaine as well as Flurb/Capsiacin/Methyl Salicylate/menthol/Lidocaine and Gabacyclotram. Other recommended treatments are Genicin, Theramine, Sentra AM, Sentra PM, and Gabadone. The requested treatments include Sentra AM and Gabadone.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Sentra AM #60:** 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 (updated 04/30/15) - Online Version, Medical food.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter/Medical food.

**Decision rationale:** According to the Official Disability Guidelines, medical food is not recommended for chronic pain. Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food as "a food which is formulated to be consumed or administered enterally 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 quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. The request for Sentra AM #60 is not medically necessary and appropriate.

**Gabadone #60:** 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 (updated 04/30/15) - Online Version, Medical food.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter/Gabadone.

**Decision rationale:** As noted in ODG, GABAdone is a Medical food that is a proprietary blend of choline bitartrate, glutamic acid, 5-hydroxytryptophan, GABA, grape seed extract, griffonia extract, whey protein, valerian extract, ginkgo biloba and cocoa. It is intended to meet the nutritional requirements for sleep disorders and sleep disorders associated with insomnia. Per ODG, Gabadone is not recommended by ODG. The request for Gabadone #60 is not medically necessary and appropriate.