

<b>Case Number:</b>	CM15-0002326		
<b>Date Assigned:</b>	01/14/2015	<b>Date of Injury:</b>	02/09/2006
<b>Decision Date:</b>	03/10/2015	<b>UR Denial Date:</b>	01/02/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/06/2015

### 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: Iowa, Illinois, Hawaii

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & Gen Prev Med

### 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 62 year old female, who sustained an industrial injury on 2/9/06. She has reported total body pain and chronic fatigue. The diagnoses have included left knee DJD, chronic lumbarsacral strain, myalgia and myositis. Treatment to date has included oral and topical medication and acupuncture. Currently, the injured worker reports total body pain and tenderness. The treating physician is requesting to continue Sentra AM two every morning, Gabadone two at bedtime, Flurbiprofen three every day and Theramine three every day. On 1/2/15 Utilization Review non-certified a prescription for Sentra AM two every morning, Gabadone two at bedtime, Flurbiprofen three ever day and Theramine three every day. The UR physician cited the ODG guidelines and MTUS guidelines for NSAIDs. On 1/6/15, the injured worker submitted an application for IMR for review of Sentra AM two every morning, Gabadone two at bedtime, Flurbiprofen three ever day and Theramine three every day.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Sentra AM 2QAM:** 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 Chapter, Sentra PM

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain, Medical Food

**Decision rationale:** Sentra AM is a medical food that contains choline and acetylcarnitine as intended to maintain production of acetylcholine in the central and peripheral nervous system. MTUS and ODG are silent specifically regarding Sentra AM. In addition ODG states that a medical food is 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 eternally 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. To be considered the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. ODG specifically states Choline is a precursor of acetylcholine. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. Medical records do not indicate that the patient meets these criteria. The medical records do not indicate the specific dietary disease or condition for which there is a distinctive nutritional requirement that the medication would be used for. Additionally, there is a component of this medication that is not recommended per guidelines. As such, the request for Sentra AM 2QAM is not medically necessary.

**Gabadone 2HS:** 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 Chapter, Gabadone

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Gabadone and Medical Food

**Decision rationale:** MTUS is silent concerning Gabadone. ODG states that a medical food is 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. ODG comments on Gabadone directly, Not recommended. Gabadone is a medical food from [REDACTED], [REDACTED], that is a proprietary blend of Choline Bitartrate, Glutamic Acid, 5-Hydroxytryptophan, and GABA. It is intended to meet the nutritional requirements for inducing sleep, promoting restorative sleep and reducing snoring in patients who are experiencing anxiety related to sleep disorders. (Shell, 2009) See Medical food, Choline, Glutamic Acid, 5-hydroxytryptophan, and Gamma-aminobutyric acid

(GABA). The ODG guidelines do not support the use of Gabadone. As such, the request for Gabadone 2HS is not medically necessary.

**Theramine 3QD:** 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 Chapter, Theramine

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Theramine and medical food

**Decision rationale:** ODG states that a medical food is 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. ODG comments on Theramine directly, not recommended. Theramine is a medical food from [REDACTED], [REDACTED], that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. See Medical food, Gamma-aminobutyric acid (GABA), where it says, There is no high quality peer-reviewed literature that suggests that GABA is indicated; Choline, where it says, there is no known medical need for choline supplementation; L-Arginine, where it says, This medication is not indicated in current references for pain or inflammation; & L-Serine, where it says, There is no indication for the use of this product. In this manufacturer study comparing Theramine to Naproxen, Theramine appeared to be effective in relieving back pain without causing any significant side effects. (Shell, 2012) Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. The ODG guidelines do not support the use of Theramine. As such, the request for Theramine 3QD is not medically necessary.

**Flurbiprofen 3QD:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-73. Decision based on Non-MTUS Citation Compound creams

**Decision rationale:** MTUS specifies four recommendations regarding NSAID use:1) Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain.2) Back Pain - Acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP.3) Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs

were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics.4) Neuropathic pain: There is inconsistent evidence for the use of these medications to treat longterm neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain. The treating physician did not document a decrease in pain or functional improvement from the use of Flurbiprofen. Long term usage is recommended against by guidelines. As such, the request for Flurbiprofen 3QD is not medically necessary.