

<b>Case Number:</b>	CM13-0059993		
<b>Date Assigned:</b>	03/03/2014	<b>Date of Injury:</b>	07/31/2010
<b>Decision Date:</b>	05/08/2014	<b>UR Denial Date:</b>	10/31/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/02/2013

### 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 and Rehabilitation, has a subspecialty in Pain Medicine, 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:

The injured worker is a 67-year-old male with a date of injury of July 31, 2010. The injured worker developed chronic pain in the neck, mid back, low back, shoulders and arms. He also reportedly developed blurry vision, G.I. distress with upset stomach, cardiovascular problems including intermittent chest pain & hypertension, psychiatric mood disorders, stress, and depression. The carrier has accepted the claims of mood disorders, cervical spine, heart, and bilateral shoulders. The disputed issues include a request for Omeprazole, unspecified fasting labs, Sentra, probiotics, and Klonopin. A utilization review determination had noncertified these requests. The stated rationale include the following: Regarding fasting labs, the provider did not specify what type of labs was requested and this was noncertified. Regarding the Omeprazole, there was a modification to once daily dosing rather than twice daily dosing, changing the quantity from 60 tablets to 30 tablets. Regarding the request for probiotics, the reviewer cited that the MTUS does not recommend such supplements "as showing any meaningful benefits in the treatment of chronic pain and only considers potential use with documented proof of nutritional deficiencies." Regarding the request for Hypertensa and the Sentra, the reviewer stated that no scientific evidence is available to establish the safety and efficacy of these medical foods.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**OMEPRAZOLE 20MG QUANTITY 60.00:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MTUS: CHRONIC PAIN MEDICAL TREATMENT GUIDELINES, NSAIDS,

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Proton Pump Inhibitors (PPI) Page(s): 68-69.

**Decision rationale:** In the case of this injured worker, there is documentation of G.I. upset. For proton pump inhibitors, a standard prophylactic dose is once daily dosing for the management of acid reflux, upset stomach, and peptic ulcers that are not actively bleeding. Twice daily dosing is typical for actively bleeding ulcers. In the case of this injured worker, there was no documentation of actively bleeding ulcers and the utilization review determination is upheld.

**RETRO FASTING LABS (UNSPECIFIED LAB TESTS):** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Labs Page(s): 23; 64.

**MAXIMUS guideline:** Decision based on MTUS ACOEM.

**Decision rationale:** Section 9792.21(c) of the California Medical Treatment Utilization Schedule states that: "Treatment shall not be denied on the sole basis that the condition or injury is not addressed by the MTUS. In this situation, the claims administrator shall authorize treatment if such treatment is in accordance with other scientifically and evidence-based, peer-reviewed, medical treatment guidelines that are nationally recognized by the medical community, in accordance with subdivisions (b) and (c) of section 9792.25, and pursuant to the Utilization Review Standards found in section 9792.6 through section 9792.10." It is unclear as to what labs are being requested. A progress note on August 13, 2013 specifies under item number 1 with the heading of "formal authorization request" for "fasting labs." There is no explanation of which specific labs are requested. There is no rationale that specifically applies to this injured worker that is provided. Rather a general statement of light laboratory tests may be needed from a citation in ACOEM is listed. This request is non-certified.

**PROBIOTICS:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**Decision rationale:** Probiotics are not specifically addressed in the California Medical Treatment and Utilization Schedule. Section 9792.21(c) of the California Medical Treatment Utilization Schedule states that: "Treatment shall not be denied on the sole basis that the condition or injury is not addressed by the MTUS. In this situation, the claims administrator shall authorize treatment if such treatment is in accordance with other scientifically and evidence-based, peer-reviewed, medical treatment guidelines that are nationally recognized by the medical

community, in accordance with subdivisions (b) and (c) of section 9792.25, and pursuant to the Utilization Review Standards found in section 9792.6 through section 9792.10." In a progress note on date of service August 13, 2013, the 3rd authorization request included for probiotics. The rationale for this medication is not supplied. This request is recommended for non-certification.

**HYPERTENSA ONE BOTTLE FOR TWO MONTHS: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Acupuncture Treatment Guidelines.

**Decision rationale:** In a progress note on date of service August 13, 2013, the 3rd authorization request included for probiotics. The rationale for this medication is not supplied. Medical foods for addressing hypertension are not accepted as standard of care. The 8th Joints National Committee for evidence-based guidelines on the management of hypertension does not support this. This request is recommended for non-certification.

**SENTRA AM ONE BOTTLE FOR ONE MONTH: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines

**Decision rationale:** Sentra AM is a medical food intended for management of chronic pain and chronic fatigue. Neither the California Medical Treatment and Utilization Schedule nor the Official Disability Guidelines support this medical food for chronic pain. There is no peer reviewed literature or national guidelines to support this. This request is not recommended.

**SENTRA PM ONE BOTTLE FOR ONE ON MONTH: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** The California Medical Treatment and Utilization Schedule does not directly address this request. The Official Disability Guidelines state the following regarding Sentra PM: "Sentra PM: Under study for insomnia. Preliminary results are promising, from a single study sponsored by the manufacturer, but independent unbiased studies are necessary for a recommendation. Sentra PM is a medical food from [REDACTED]"

████████████████████, intended for use in management of sleep disorders, that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. In a RCT published in a pay-to-publish journal, and written by employees of the marketer of Sentra PM, the authors concluded that Sentra PM can improve the quality of sleep, the response to trazodone as a sleep medication and parasympathetic autonomic nervous system activity. (Shell, 2012) See also Insomnia treatment, where it says there is limited evidence to support trazodone for insomnia, but it may be an option in patients with coexisting depression. See also Sentra PM in the Pain Chapter." Given the lack of evidence for this medical food, this request is recommended for noncertification.

**KLONOPIN (UNSPECIFIED DOSAGE/QUANTITY): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines on page 24 states the following regarding benzodiazepines: "Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. (Baillargeon, 2003) (Ashton, 2005)" The documentation submitted includes a progress note on date of service September 19, 2013. The patient sees a psychiatrist and psychotherapist on a regular basis. This note indicates that the patient takes 4 mg of Klonopin at bedtime. He is also noted to be on an SSRI. In follow-up documentation, there is no documentation of efficacy of this medication. The guidelines only recommend short-term usage of benzodiazepines. Progress notes from December 23, 2013 indicate that the patient is still on Klonopin. This timeline is inappropriate and this request is recommended for non-certification.