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| <b>Case Number:</b>   | CM15-0172619 |                              |            |
| <b>Date Assigned:</b> | 09/22/2015   | <b>Date of Injury:</b>       | 09/13/2011 |
| <b>Decision Date:</b> | 12/18/2015   | <b>UR Denial Date:</b>       | 08/27/2015 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 09/01/2015 |

### 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: Preventive Medicine, Occupational 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 is a 54 year old female, who sustained an industrial injury on 9-13-2011. The injured worker was diagnosed as having lumbar radiculopathy and lumbar facet syndrome. Treatment to date has included diagnostics and medications. On 8-06-2015, the injured worker complains of "no change in her symptoms", noting constant low back pain with radiation to her lower extremities, rated 7 out of 10 (rated 7-8 out of 10 on 6-25-2015 and 8 out of 10 on 5-28-2015). No other complaints were specified on 8-06-2015. Objective findings included blood pressure 148 over 92 and pulse 85. Exam of the lumbar spine noted decreased range of motion, tenderness to palpation along the lumbar spine, positive straight leg raise on the left, and Kemp's positive bilaterally. Sensory exam of the lower extremities noted decreased sensation to light touch over the L5 to S1 nerve root along the left lower extremity. Magnetic resonance imaging of the lumbar spine (7-23-2015) was documented to show a slight broad right apical curvature, L4-L5: 3mm disc bulge with mild to moderate central and neural foraminal stenosis, with the disc indenting the thecal sac, L5-S1: 3mm broad right greater than left bulge with moderate right greater than left neural foraminal stenosis, central canal mildly stenotic, and L3-L4: 2mm bulge with mild central and neural foraminal stenosis. Current medication regimen was not specified. Work status was total temporary disability. The use of Ambien, topical compound medications and supplements was noted since at least 5-28-2015. Urine toxicology (6-25-2015) was inconsistent with Ambien use. The treatment plan included Ambien 10mg #30, topical compound cream medications, Alph Lipoic Acid 12.5mg -Folic Acid 0.5mg-Hyaluronic Acid -Methylcobalamin (B12) 0.5 mg-Pyridoxal 5-Phosphate 35 mg -Resveratrol 25 mg -Ubiquinol

(CoQ10) 50 mg- Vitamin D3 5000 IU, Theramine #180, Sentra AM #60, Sentra PM #60, Gabadone #60, and electromyogram and nerve conduction studies of the lower extremities. On 8-27-2015 Utilization Review non-certified the requested Ambien, topical compound cream medications and supplements, and modified the requested electrodiagnostic studies to only EMG of the lower extremities.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Ambien 10 mg #30:** 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 (Chronic): Zolpidem (Ambien), 2015.

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

**Decision rationale:** The Official Disability Guidelines do not recommend the use of sleeping pills for long-term use. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. The patient has been taking Ambien for longer than the 2-6 week period recommended by the ODG. Ambien 10 mg #30 is not medically necessary.

**Ket/Gaba/Bup/Flut/Bac/Cyclo/Cloni/Hyauronic Acid 10/6/5/1/2/2/0.2/0.2% topical cream:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** According to the MTUS, there is little to no research to support the use of many of these compounded topical analgesics. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Ketoprofen agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis.

Ket/Gaba/Bup/Flut/Bac/Cyclo/Cloni/Hyauronic Acid 10/6/5/1/2/2/0.2/0.2% topical cream is not medically necessary.

**Alph Lipoic Acid 12.5mg -Folic Acid 0.5mg-Hyaluronic Acid /Methylcobalamin (B12) 0.5 mg-Pyridoxal 5-Phosphate 35 mg -Resveratrol 25 mg -Ubiquinol (CoQ10) 50 mg- Vitamin D3 5000 IU:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Evaluation, Treatment and Prevention of Vitamin D Deficiency: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2011 Jul; 96(7): 1911-30.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** According to the MTUS, there is little to no research to support the use of many of these compounded topical analgesics. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Alph Lipoic Acid 12.5mg -Folic Acid 0.5mg-Hyaluronic Acid /Methylcobalamin (B12) 0.5 mg-Pyridoxal 5-Phosphate 35 mg -Resveratrol 25 mg -Ubiquinol (CoQ10) 50 mg- Vitamin D3 5000 IU is not medically necessary.

**Theramine #180:** 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 (Chronic): Theramine (2015).

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

**Decision rationale:** Theramine is a medical food. Medical food is 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 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. Medical foods do not have to be registered with the FDA and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. The medical documents provided do not clearly specify the disease or condition for which the requested distinctive nutritional ingredient is intended to treat, nor is there evidence that testing of the nutritional ingredient using recognized scientific principles has been completed. Theramine #180 is not medically necessary.

**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 (Chronic): Medical Food (2015).

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

**Decision rationale:** Sentra AM is a medical food. Medical food is 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 internally 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. Medical foods do not have to be registered with the FDA and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. The medical documents provided do not clearly specify the disease or condition for which the requested distinctive nutritional ingredient is intended to treat, nor is there evidence that testing of the nutritional ingredient using recognized scientific principles has been completed. Sentra AM #60 is not medically necessary.

**Sentra PM #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 (Chronic): Medical Food (2015).

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

**Decision rationale:** Sentra PM is a medical food. Medical food is 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 internally 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. Medical foods do not have to be registered with the FDA and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. The medical documents provided do not clearly specify the disease or condition for which the requested distinctive nutritional ingredient is intended to treat, nor is there evidence that testing of the nutritional ingredient using recognized scientific principles has been completed. Sentra PM #60 is not medically necessary.

**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 (Chronic): Medical Food and GABAdone (2015).

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

**Decision rationale:** Gabadone is a medical food. Medical food is 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 internally 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. Medical foods do not have to be registered with the FDA and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. The medical documents provided do not clearly specify the disease or condition for which the requested distinctive nutritional ingredient is intended to treat, nor is there evidence that testing of the nutritional ingredient using recognized scientific principles has been completed. Gabadone #60 is not medically necessary.

**Pentoxifyline/Aminophylline/Lidocaine/Hyaluronic Acid 5/3/2.5/1% cream, 240gm:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** According to the MTUS, there is little to no research to support the use of many of these compounded topical analgesics. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Pentoxifyline/Aminophylline/Lidocaine/Hyaluronic Acid 5/3/2.5/1% cream, 240gm is not medically necessary.

**NCV/EMG of the lower extremities:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Low Back Complaints 2004. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Low Back-Lumbar & Thoracic (Acute & Chronic): Electrodiagnostic studies (EDS) and Nerve conduction studies (NCS).

**MAXIMUS guideline:** Decision based on MTUS Low Back Complaints 2004, Section(s): Special Studies.

**Decision rationale:** The ACOEM Guidelines state that electromyography (EMG), including H-reflex tests, may be useful to identify subtle, focal neurologic dysfunction in patients with low back symptoms lasting more than three or four weeks. There is no presumptive diagnosis of peripheral nerve compression and there is no clear documentation of how this test result will change the treatment plan. Detailed evidence of severe and/or progressive neurological abnormalities has not been documented. NCV/EMG of the lower extremities is not medically necessary.