

<b>Case Number:</b>	CM15-0182007		
<b>Date Assigned:</b>	10/14/2015	<b>Date of Injury:</b>	06/14/2008
<b>Decision Date:</b>	12/17/2015	<b>UR Denial Date:</b>	08/18/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/16/2015

### 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: New York

Certification(s)/Specialty: Anesthesiology

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This injured worker is a 55 year old female, who sustained an industrial injury on 06-14-2008. The injured worker was diagnosed as having lumbago, thoracic-lumbosacral neuritis-radiculitis unsp, degenerative disc disease lumbar -lumbosacral. On medical records dated 08-05-2015, the subjective complaints were noted as lower back pain and right shoulder pain. Pain was radiating to her bilateral buttocks and to groin. Pain with medication was noted as 5 out of 10 and without medication a 9 out of 10. Objective findings were noted as lumbar tenderness to palpation - midline, lumbar level L2-S1 revealed tenderness over the facet joints at L3 to S1 bilaterally with positive provocation test. Sacral area was noted to have tenderness to palpation, SI joint tenderness to palpation was noted bilaterally. Muscle spasm were noted in the lumbar paravertebral, quadratus lumborum, gluteus medius, gluteus maximus and piriformis muscles and straight leg raise was noted positive bilaterally. Treatments to date included medication and injections. Current medications were listed as Ultram. The Utilization Review (UR) was dated 08-18-2015. A request for bilateral sacroiliac joint injection under fluoroscopy and arthrogram, Percura #120, Sentra PA #60, Theramine #90, Trepadone #120, Compound Medication: Tramadol-Baclofen in Lidoderm, 60gms and Compound Medication: Flurbiprofen-Gabapentin-Lidocaine in lipoderm was submitted. The UR submitted for this medical review indicated that the request for Bilateral sacroiliac joint injection under fluoroscopy and arthrogram, Percura #120, Sentra PA #60, Theramine #90, Trepadone #120 , Compound Medication: Tramadol-Baclofen in Lidoderm, 60gms and Compound Medication: Flurbiprofen-Gabapentin-Lidocaine in lipoderm, 60gms was non-certified.

## IMR ISSUES, DECISIONS AND RATIONALES

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

### **Bilateral sacroiliac joint injection under fluoroscopy and arthrogram: 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), Hip & Pelvis (Acute & Chronic): Sacroiliac joint blocks.

**MAXIMUS guideline:** Decision based on MTUS Low Back Complaints 2004, Section(s): Diagnostic Criteria. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) SIJ blocks.

**Decision rationale:** Sacroiliac joint injections (SIJ) are recommended as an option if the patient has failed at least 4-6 weeks of aggressive conservative therapy. Sacroiliac dysfunction is poorly defined and the diagnosis is often difficult to make due to the presence of other low back pathology (including spinal stenosis and facet arthropathy). The diagnosis is also difficult to make as pain symptoms may depend on the region of the SI joint that is involved (anterior, posterior, and/or extra-articular ligaments). Pain may radiate into the buttock, groin and entire ipsilateral lower limb, although if pain is present above L5, it is not thought to be from the SI joint. Criteria for the use of SIJ blocks include that the patient has had and failed at least 4-6 weeks of aggressive conservative therapy including, physical therapy (PT), home exercise and medication management. In this case, it is unclear if the patient's pain pattern is due to SI joint dysfunction. There was no documentation of positive exams with regard to the SIJ in the latest progress notes submitted. In addition, it appears that this patient had SIJ injections in the past without any significant objective functional improvement. Medical necessity for the bilateral SIJ injections has not been established. The requested bilateral procedure not medically necessary.

### **Percura, #120: 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.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medscape Internal Medicine (2014).

**Decision rationale:** According to Medscape, Percura, an amino acid mixture, is a medical food product indicated for clinical dietary management of the metabolic processes of pain, inflammation and loss of sensation due to peripheral neuropathy. According to the ODG guidelines, a medical food is not recommended for 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." Medical necessity for the requested item has not been established. The requested medical food 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): Sentra PM.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Sentra Product Information.

**Decision rationale:** Sentra PM is a Medical food that is intended for use in the management of sleep disorders associated with depression. It is a proprietary blend of choline bitartate, glutamate, and 5-hydroxytryptophan. There is no support for the use of medical food in the treatment of chronic pain, and there was no indication for the need for supplementation of any of the ingredients. Medical necessity for the requested item has not been established. The requested medical food is not medically necessary.

**Theramine, #90:** 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.

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

**Decision rationale:** According to the ODG, Theramine is an FDA regulated medical food designed to address the increased nutritional requirements associated with chronic pain syndromes and low back pain. Its mechanism of action is the production of neurotransmitters that help manage and improve the sensory response to pain and inflammation. This medication contains 5-hydroxytryptophan 95%, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine, gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa. There is no medical literature that supports the use of this medication for the treatment of chronic pain. Medical necessity for the requested medication has not been established. The requested medication is not medically necessary.

**Trepadone, #120:** 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): Trepadone.

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

**Decision rationale:** According to the CA MTUS, all chronic pain therapies are focused on the goal of functional restoration rather than merely the elimination of pain, and assessment of treatment efficacy is accomplished by reporting functional improvement. The MTUS Guidelines define functional improvement as "a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management...and a reduction in the dependency on continued medical treatment." The MTUS is silent on the use of Trepadone. The ODG states that Trepadone is a medical food with insufficient evidence to support its use for osteoarthritis or for neuropathic pain, and is not recommended. The guidelines note that medical foods are not recommended for chronic pain as they have not been shown to produce meaningful benefit or functional improvement. Therefore, based on the guidelines, the request for Trepadone is not medically necessary.

**Compound Medication: Tramadol/Baclofen in lipoderm, 60gms: 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 California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, the compounded topical analgesic contains: Tramadol/Baclofen in Lipoderm. Lipo-max (or Lipo-derm) cream is only available from the Professional Compounding Centers of America (PCCA). The PCCA base has the ability to deliver four (4) drugs at once. Tramadol is not FDA approved for a topical application. There is no peer-reviewed literature to support its use. Medical necessity for the requested compounded topical analgesic has not been established. The requested treatment is not medically necessary.

**Compound Medication: Flurbiprofen/Gabapentin/Lidocaine in lipoderm, 60gms: 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 California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, the compounded topical analgesic contains: Flurbiprofen/ Gabapentin/ Lidocaine in Lipoderm. Lipo-max (or Lipo-derm) cream is only available from the Professional Compounding Centers of America (PCCA). The PCCA base has the ability to deliver four (4) drugs at once. There are no clinical studies to support the safety or effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic). Medical necessity for this topical analgesic containing Flurbiprofen, Gabapentin, and Lidocaine in Lipoderm cream, has not been established. The request for the compounded topical analgesic cream is not medically necessary.