

<b>Case Number:</b>	CM14-0129147		
<b>Date Assigned:</b>	08/20/2014	<b>Date of Injury:</b>	06/26/2009
<b>Decision Date:</b>	01/14/2015	<b>UR Denial Date:</b>	08/01/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/13/2014

### 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 & Rehabilitation, has a subspecialty in Interventional Spine 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 patient is a 65 year old female with an injury date of 06/26/09. The patient is status post lumbar left L5-S1 discectomy on 10/12/10 and bilateral L3, L4, L5 laminectomy and revision of L5-S1 laminectomy on 09/14/12, per progress report dated 12/09/13. Based on 06/30/14 progress report, she complains of pain in low back, leg, foot and shoulder. The constant sharp, shooting and throbbing pain is rated at 8/10. The low back pain is radiating to the lower extremities. Physical examination of the lumbar spine reveals tenderness to palpation in the bilateral paravertebral regions at L4-5 and L5-S1. Range of motion is restricted with the patient experiencing pain during extension, right lateral rotation, and left lateral rotation. Straight leg raise is positive bilaterally. As per progress report dated 05/30/14, the patient rates her pain as 10/10. Current medications include Hydrocodone, Theramine and amitriptyline, as per progress report dated 06/30/14. The patient has tried physical therapy and epidural steroid injections and experienced some relief, as per progress report dated 03/17/14. MRI of the Left Hip, 11/18/13:- Marked joint space narrowing demonstrated superiorly within the left hip- Strain in the distal left gluteus medius tendon at insertion- Right hip trochanteric bursitis MRI of the Lumbar Spine, 03/25/13, as per progress report dated 03/17/14:- Small broad-based disc protrusion at L1-L2- Annular disc bulge at L2-L3- Mild bilateral facet joint hypertrophic changes at L3-4- Post posterior decompression of the central spinal canal at L3-4 and L4-5 with post-surgical soft tissue enhancement- Left L5-S1 laminectomies with decreased post-surgical perinueral soft tissue enhancement The treater is requesting for (a) Hydrocodone 10/325 mg (1 2 x DAY) (b) Theramine (1-3 2 x DAY). The utilization review determination being challenged is dated 08/01/14. The rationale follows:(a) Hydrocodone 10/325 mg (1 2 x DAY) - "In this case, the criteria have not been met with insufficient documentation regarding improvement to pain and

function and long term opioid use research is limited." (b) Theramine (1-3 2 x DAY) - "There is insufficient data supporting efficacy of this product." Treatment reports were provided from 08/22/13 - 06/30/14.

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

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

**HYDROCODONE 10/325MG:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Criteria For Use Of Opioids Page(s): 60-61, 76-78 and 88-89.

**Decision rationale:** The patient is status post lumbar left L5-S1 discectomy on 10/12/10 and bilateral L3, L4, L5 laminectomy and revision of L5-S1 laminectomy on 09/14/12, per progress report dated 12/09/13 and she complains of pain in low back, leg, foot and shoulder rated at 8/10, as per progress report dated 06/30/14. The request is for HYDROCODONE 10/325 mg (1 2 x DAY). MTUS Guidelines pages 88 and 89 states, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS page 78 also requires documentation of the 4As (analgesia, ADLs, adverse side effects, and adverse behavior), as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. A review of the available progress reports indicates that this is the first prescription for Hydrocodone. However, in progress report dated 06/30/14, the treater states that "The patient's Norco was refilled as indicated as it does decrease her level of pain and improve function." Nonetheless, the treater does not discuss specific changes in the pain scale and improvement in activities of daily living before and after taking Norco. A urine drug screen dated 03/17/14 was consistent but there is no discussion about the side effects of the medication as well. Since impact of Norco (a combination of Hydrocodone and acetaminophen) is not clear with regards to the 4As including analgesia, specific ADL's, adverse reactions, and aberrant behavior, a new request for Hydrocodone IS NOT medically necessary.

**THREAMINE:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines

**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) and topic 'Medical Foods' Other Medical Treatment Guideline or Medical Evidence:

**Decision rationale:** The patient is status post lumbar left L5-S1 discectomy on 10/12/10 and bilateral L3, L4, L5 laminectomy and revision of L5-S1 laminectomy on 09/14/12, per progress

report dated 12/09/13. She complains of pain in low back, leg, foot and shoulder rated at 8/10, as per progress report dated 06/30/14. The request is for Theramine (1-3 2 x DAY). MTUS and ACOEM guidelines are silent on medical foods. However, ODG guidelines, chapter 'Pain (Chronic)' and topic 'Medical Foods', state that medical foods such as Theramine are "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." In this case, the treater is requesting Theramine, a medical food containing a proprietary formulation of neurotransmitter precursors (L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan), neurotransmitters (gamma-aminobutyric acid [GABA]), and a neuromodulator (L-serine); polyphenolic antioxidants (grape seed extract, cinnamon bark, cocoa); anti-inflammatory and immunomodulatory peptides (whey protein hydrolysate); and adenosine antagonists (cocoa, metabromine), as per <http://www.nutrientpharmacology.com/PDFs/monographs/theramine-monograph.pdf>. In progress report dated 07/30/14, the treater states that Theramine is "for the effective treatment of the patient's chronic pain and avoiding high dose NSAID / Opioid / Muscle Relaxant therapy." The treater also states that "Theramine stimulates the production of neurotransmitters such as serotonin, GABA, norepinephrine, nitric oxide and acetylcholine. If the timing and secretion of the neurotransmitters are effectively modulated, acute and chronic pain disorders are more effectively managed." While the ODG guidelines do not discuss every ingredient found in Theramine, they state that L-arginine is "not indicated in current references for pain or 'inflammation.'" Regarding L-serine, the guidelines state "There is no indication in Micromedex, Clinical Pharmacology, or AltMedDex for the use of this supplement." Regarding GABA, the guidelines state that "This supplement is indicated for epilepsy, spasticity and tardive dyskinesia. There is no high quality peer-reviewed literature that suggests that GABA is indicated for treatment of insomnia. Adverse reactions associated with treatment include hypertension, increased heart rate and anxiety." Additionally, the guidelines do not recommend medical foods for the treatment of chronic pain. Thus, Theramine IS NOT medically necessary.