

<b>Case Number:</b>	CM14-0149630		
<b>Date Assigned:</b>	09/18/2014	<b>Date of Injury:</b>	12/25/2005
<b>Decision Date:</b>	10/21/2014	<b>UR Denial Date:</b>	08/15/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/15/2014

### 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 Occupational 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:

Patient is a 47-year-old male who has submitted a claim for mild chronic low back strain with disc protrusion at L2-3, L3-4 and L5-21; right knee medial meniscus tear; s/p left total knee arthroplasty (02/04/14); and status post left middle finger trigger release (01/23/13), associated with an industrial injury date of 12/25/05. Medical records from 2013 to 2014 were reviewed. Patient apparently sustained his injury on 12/25/05. However, the mechanism of the initial injury was not described in the submitted records. Latest progress report of 10/05/14 was handwritten and difficult to make out. 07/03/14 progress report showed patient had complaint of sharp pain in his left middle finger whenever he grips, grasps or holds onto the steering wheel while driving, with associated tingling and numbness at the distal area and radiating to the elbow as well as note of a painful lump at the distal joint and enlargement of the 3rd proximal joint. Patient also has constant sharp, shooting pain in the lower back radiating to his left leg and toes with associated numbness and tingling, aggravated by prolonged standing, walking and sitting. He has difficulty bending forward, backward, sideways and prolonged driving. He has difficulty sleeping and is frequently awakened by pain and discomfort. He also reports continuous dull and sharp pain in both knees, with swelling and warmth to touch. He has difficulty standing, walking, ascending and descending stairs for a prolonged period, with painful clicking and popping in his right knee and walks with an uneven gait. He has difficulty performing his ADLs. On physical examination, there was tenderness over the left 3rd volar metacarpo-phalangeal joint, with mildly restricted ROM of the 1st left and right finger; antalgic gait with mild right knee and moderate left knee pain on walking heel-to-toe; para-spinal muscle and spinous process tenderness with muscle guarding of the lumbar spine and normal ROM; popping, crepitus and pain during ROM of the knees bilaterally and positive for McMurray's and Apley's test bilaterally; and note of the left lower extremity being 2cm longer than the right. Motor and sensory examinations are

normal. Plan was to place patient on work restriction and to continue medications. Treatment to date has included surgery and medications (Norco and Protonix since at least 10/01/13; Benical since at least 3/18/14 and Lentra since 10/05/14). Utilization review date of 08/15/14 denied the request for Lentra 20mg #60 because the documentation does not show medical necessity for dietary supplementation with Lentra, as well as absence of scientific evidence showing that dietary deficiency of above compounds would present symptoms as described in the current clinical scenario.

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

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

#### **Lentra 20mg #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 Chapter, Medical Food Section

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Medical food section Other Medical Treatment Guideline or Medical Evidence: Manufacturer's website, Lentra by Sanesco

**Decision rationale:** Per the manufacturer's website: "Lentra by Sanesco is a specially crafted GABA receptor formula that activates inhibitory neurotransmission. By doing so the body feels much less tense and in a comfortable tranquil mood. The specific target of Lentra is GABA-A receptors. When GABA ranges fall below normal ranges nervous feelings and irritability have been said to sometimes occur. Also when body serotonin levels decrease GABA levels increase in order to balance out the body. When serotonin increases as a result GABA levels go back down. Lentra can work to address this seesaw-like issue by keeping the balance between the inhibitory systems to keep it at a calm medium. Lentra contains Magnesium 22 mg, Taurine 250 mg, L-theanine 75 mg, Lactium 75 mg, NSB 102.5 mg (a proprietary blend of protease amylase lipase and BioPerine standardized for 95% piperine from piper nigrum)". The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the Official Disability Guidelines, (ODG), Pain Chapter, Medical food section was used instead. 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. 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." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. In this case, patient was started on Lentra on 10/05/14. There was no rationale given as to why the patient needed this supplementation. There was no mention of nutritional deficiency, nor was there mention of signs of anxiety or agitation. Likewise, medical foods are not recommended by guidelines due to absence of quality studies demonstrating its

benefits, safety or efficacy. Therefore, the request for Lentra 20mg #60 is not medically necessary.