

<b>Case Number:</b>	CM14-0195327		
<b>Date Assigned:</b>	12/03/2014	<b>Date of Injury:</b>	08/15/2010
<b>Decision Date:</b>	01/15/2015	<b>UR Denial Date:</b>	11/12/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/21/2014

### 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 Family Practice and is licensed to practice in Ohio. 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 65 year old male injured worker suffered an industrial accident on 8/15/2010 when he struck his right knee against a door. The diagnoses were right knee internal derangement, lumbar spine stenosis and depression. The past treatments included physical therapy, right knee arthroscopy (4/1/2011), Synvisc injections (10-2011), medications, and acupuncture. On the visit of 9/4/2014 the injured worker complained of frequent, moderate pain of right knee and lumbar spine. The exam revealed painful and decreased range of motion of the right knee and the lumbar muscles were tender upon palpation. The physician prescribed Sintralyne 30 capsules nightly. The medical records provided did not include signs and symptoms or indications for use of this medication. The UR decision of 11/12/2014 cited that this medication was a medical food or nutritional supplement without evidence of efficacy. Also absent was description of any sleep dysfunction or objective testing.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Sintralyne-Cap PM # 30 Supply: 30 days: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 77, 111-113. Decision based on Non-MTUS Citation ODG, Treatment Index, 12th Edition (web), 2014, Chronic Pain-Medical food, US National Institute of health (NIH) National Library of Medicine (NLM) PubMed, 2014 (<http://www.ncbi.nlm.nih.gov/pubmed/>)

**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 foods

**Decision rationale:** Sintralyne PM is a proprietary formulation containing gamma-aminobutyric acid, hawthorn, kava, chamomile flower, lemon balm, valerian passion flower, and tryptophan derivatives. This product is considered a medical food. 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 instance, the treating physician does not provide the rationale for the prescription of Sintralyne PM and it is thus presumed that the purpose is for chronic pain. As a medical food, Sintralyne PM is not medically necessary per the referenced guidelines.