

<b>Case Number:</b>	CM15-0076787		
<b>Date Assigned:</b>	04/28/2015	<b>Date of Injury:</b>	10/27/2008
<b>Decision Date:</b>	05/28/2015	<b>UR Denial Date:</b>	04/11/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/21/2015

### 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: Pennsylvania

Certification(s)/Specialty: Internal Medicine, Hospice & Palliative 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 48-year-old male, with a reported date of injury of 10/27/2008. The diagnoses include lumbar musculoligamentous sprain/strain, status post lumbar spine surgery, lumbar spine facet hypertrophy, and lumbar disc herniation at L4-5 and L5-S1. Treatments to date have included a computerized tomography (CT) scan of the lumbar spine, an MRI of the lumbar spine, an x-ray of the lumbar spine, and home exercise program. The progress report dated 02/20/2015 was handwritten and somewhat illegible. The report indicates that the injured worker complained of constant lumbar spine pain. The objective findings include lumbar flexion at 10 degrees, L3-4 disc protrusion, moderate hypertrophic changes at L4-5, L5-S1 disc protrusion, and moderate hypertrophic facet changes according to the CT scan. The treating physician requested Sintralayne PM (unknown amount dispensed on 02/20/2015).

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Sintralayne PM, unknown amount dispensed 2/10/15: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Medical Food.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pharmaceutica North America Inc. Sintralyne-PM, <http://www.pnarx.com/index.php/sintralyne-pm>, accessed 05/23/2015.

**Decision rationale:** Sintralyne-PM is a medicinal food that contains melatonin, Gamma-Aminobutyric Acid (GABA), hawthorn berry, kava-kava (*piper methysticum*), chamomile flower, lemon balm (*melissa officinalis*), valerian, passion flower, and L-tryptophan. The MTUS Guidelines are silent on this issue. However, the Guidelines require that the use of treatments be scientific and evidence-based. The evidence-based literature does not support the use of this product. The submitted and reviewed documentation indicated the worker was experiencing lower back pain that went into the legs with numbness and lower abdominal pain. There was no discussion describing special circumstances that sufficiently supported this request. In the absence of such evidence, the current request for an indefinite supply of Sintralyne-PM that was dispensed on 02/10/2015 is not medically necessary.