

<b>Case Number:</b>	CM13-0039955		
<b>Date Assigned:</b>	12/20/2013	<b>Date of Injury:</b>	07/19/2011
<b>Decision Date:</b>	02/18/2014	<b>UR Denial Date:</b>	10/07/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/28/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Psychiatry 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 physician 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:

This case involves a 38 year old female. She has been diagnosed with morbid obesity and obstructive sleep apnea. Date of injury was 7-19-11. She has been diagnosed with severe depression as well as anxiety. The patient has also been given a range of dates over which she experienced her injury not just 7-19-11. The patient has been given NSAID's and has had abdominal pain. She has headaches and muscle spasms as a result of her work related injury. She has complained of insomnia. The present issue is the medical necessity of Sentra AM, Sentra PM, and gaboxetine.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retrospective request for 60 Sentra AM:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mental Illness & Stress.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation the FDA list of approved drugs, [http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchResuIts\\_Browse&StartRow=101&StepSize=100](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchResuIts_Browse&StartRow=101&StepSize=100)

**Decision rationale:** The CA MTUS is silent on Sentra AM. Although the ODG discusses Sentra PM, the ODG is silent on Sentra AM. Sentra AM (like Sentra PM) is not listed on the FDA website of approved drugs. Given the lack of mention in MTUS, ODG and FDA, Sentra AM must be seen as not medically necessary per guidelines.

**Retrospective request for 60 Sentra PM:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mental illness and stress

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mental Illness and stress chapter, section on Sentra PM and the FDA list of approved drugs,  
[http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchResults\\_Browse&StartRow=101&StepSize=100](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchResults_Browse&StartRow=101&StepSize=100)

**Decision rationale:** The CA MTUS is silent on Sentra PM. The Official Disability Guidelines (ODG) Mental Illness and stress chapter, Section on Sentra PM, which has the following to state about Sentra PM: "Under study for insomnia. Preliminary results are promising, from a single study sponsored by the manufacturer, but independent unbiased studies are necessary for a recommendation. Sentra PM is a medical food from [REDACTED] (aka [REDACTED]), [REDACTED] intended for use in management of sleep disorders, that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. In a RCT [randomized controlled trial] published in a pay-to-publish journal, and written by employees of the marketer of Sentra PM, the authors concluded that Sentra PM can improve the quality of sleep, the response to trazodone as a sleep medication and parasympathetic autonomic nervous system activity. (Shell, 2012) See also Insomnia treatment, where it says there is limited evidence to support trazodone for insomnia, but it may be an option in patients with coexisting depression. See also Sentra PM in the Pain Chapter." While the ODG mentions Sentra favorably, ODG points out that Sentra PM is still under study. The FDA has not approved Sentra PM at the following website:  
[http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchResults\\_Browse&StartRow=101&StepSize=100](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchResults_Browse&StartRow=101&StepSize=100) Because of lack of FDA approval, and because of its experimental status, Sentra PM is not medically necessary.

**Retrospective request for Gaboxetine:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mental Illness & Stress.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation FDA list of approved drugs,  
[http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchResults\\_Browse&StartRow=101&StepSize=100](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchResults_Browse&StartRow=101&StepSize=100)

**Decision rationale:** This drug has not been found by the FDA to be safe and effective. The CA MTUS and the ODG are silent on gaboxetine. Although the ingredient fluoxetine is FDA approved, the combination of choline and fluoxetine is not. According to drugs.com, there is no drug interaction between fluoxetine and choline. According to the FDA website [http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchResults\\_Browse&StartRow=101&StepSize=100](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchResults_Browse&StartRow=101&StepSize=100) Gaboxetine is not FDA approved. Given that it is not in the CA MTUS, ODG, or FDA list of approved meds, guidelines indicate Gaboxetine is not medically necessary.