

<b>Case Number:</b>	CM15-0188524		
<b>Date Assigned:</b>	09/30/2015	<b>Date of Injury:</b>	05/07/2007
<b>Decision Date:</b>	11/13/2015	<b>UR Denial Date:</b>	09/03/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/24/2015

### 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: California, Arizona, Maryland  
 Certification(s)/Specialty: Psychiatry

### 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 is a 65-year-old male with a date of industrial injury 5-7-2007. The medical records indicated the injured worker (IW) was treated for major depressive disorder; cognitive disorder, not otherwise specified; and anxiety disorder, not otherwise specified. In the progress notes (5-11-15 and 8-27-15), the IW reported improvement in his pain syndrome since his spinal surgery, but continued to have "a lot of" pain and felt depressed, disappointed and irritable. He reported an improved attitude. He continued to have a disrupted sleep pattern. He was taking Pristiq and Seroquel. Objective findings (8-27-15 notes), included clinical presentation and mental status improved from the last visit. He was in relatively good spirits, communicated well and showed no obvious cognitive problem. He was anxious and the IW and his wife related that the anti-depressants he was taking were not helping the chronic depression, irritability and insomnia; Nuvigil was no longer effective, per the provider's notes. Treatments included physical therapy and aqua therapy for lumbar pain and psychotherapy. The provider's treatment plan included a trial of Nuedexta. A Request for Authorization dated 8-27-15 was received for Nuedexta one full tab every morning for one week, then twice daily for treatment of major depression (with unspecified refills), quantity: 50. The Utilization Review on 9-3-15 non-certified the request for Nuedexta one full tab every morning for one week, then twice daily for treatment of major depression (with unspecified refills), quantity: 50.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Nuedexta, one full tab q.a.m. for one week, then b.i.d. for treatment of major depression (with unspecified refills) QTY: 50: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Mental Illness and Stress, Nuedexta.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness & Stress/Nuedexta.

**Decision rationale:** Per ODG, "Nuedexta: Not recommended. The FDA has approved this treatment for pseudobulbar affect (PBA) in adults (Nuedexta, Avanir Pharmaceuticals Inc), a combination of dextromethorphan hydrobromide and quinidine sulphate. PBA is seen in a number of neurologic conditions and is characterized by sudden and uncontrollable bouts of laughing or crying that is either unrelated or disproportionate to the emotional state of the patient. This agent has been studied to date in patients with multiple sclerosis (MS) and amyotrophic lateral sclerosis (ALS). PBA occurs when neurological disorders such as MS or stroke damage areas of the brain involved in the control of normal expression of emotion. Although it is not a life-threatening condition, it can have a significant effect on the patient's ability to interact normally in society and their relationships. Nuedexta is not suitable for treating episodes of laughing or crying brought on by mood swings and not due to pseudobulbar affect. (FDA, 2012) There are no quality published studies of the off label use of Nuedexta to treat chronic neuropathic pain. There had been a study initiated to compare the effectiveness of dextromethorphan at reducing hyperalgesia in individuals addicted to opioids, but this study was discontinued. (NCT, 2008)" The request for Nuedexta, one full tab q.a.m. for one week, then b.i.d. for treatment of major depression (with unspecified refills) QTY: 50 is not medically as this medication is not indicated for treatment of Major Depressive Disorder. The use of Nuedexta is off label in this case and thus is not medically necessary.