**Nuedexta (dextromethorphan/quinidine) Prior Approval Criteria**  
November 2016

**Definition:** Nuedexta, a combination product containing dextromethorphan hydrobromide (DM) and quinidine sulfate, is indicated for the treatment of pseudobulbar affect (PBA). DM is a sigma-1 receptor agonist and an uncompetitive N-methyl-D-aspartate (NMDA) receptor antagonist. Quinidine increases plasma levels of DM by competitively inhibiting cytochrome P450 (CYP) 2D6, which catalyzes a major biotransformation pathway for DM. The mechanism by which DM exerts therapeutic effects in patients with PBA is unknown.

**POLICY STATEMENT**  
Coverage of Nuedexta is recommended in those who meet the following criteria:

**Food and Drug Administration (FDA)-Approved Indications**

1. **Treatment of Pseudobulbar Affect (PBA).** [Note: PBA is also known as pathological laughing and crying, affective lability, emotional incontinence, emotionalism, and IEED.] Approve.

**CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Coverage of Nuedexta is recommended in circumstances that are listed in the Recommended Authorization Criteria above. The following provides rationale for specific Exclusions. This is not an exhaustive list of Exclusions.

1. **Neuropathic Pain.** Limited published data are available in patients (n = 36) with diabetic peripheral neuropathic (DPN) pain (open-label tolerability study). The available study was conducted with the DM 30 mg/quinidine 30 mg formulation, using daily doses up to DM 120 mg/quinidine 120 mg (dose cannot be achieved with Nuedexta capsules). Higher daily doses of DM and quinidine (60 mg/60 mg and 90 mg/60 mg [doses cannot be achieved with Nuedexta capsules]) have also been evaluated in patients with DPN pain (n = 379) in one Phase III, randomized, placebo-controlled 13-week study. Both DM/quinidine treatment groups had significant reductions in mean daily pain scores vs. placebo overall, as well as at Day 30, 60, and 90. More data are needed to define the place in therapy of Nuedexta in the treatment of neuropathic pain.

2. **Heroin Detoxification.** Limited published data are available in patients undergoing heroin detoxification. The available study was conducted with the DM 30 mg/quinidine 30 mg formulation, using daily doses of DM 60 mg/quinidine 60 mg (dose cannot be achieved with Nuedexta capsules). There were no differences between DM/quinidine and placebo with regard to reducing opioid withdrawal symptoms.
3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

**Approval Duration**

Approval = 365 days (1 year)

**References**