



Prior Authorization Approval Criteria

Nuedexta (dextromethorphan/Quinidine)

Generic name:	Dextromethorphan/Quinidine
Brand name:	Nuedexta
Medication class:	CNS agents; NMDA Receptor Antagonists
FDA-approved uses:	treatment of pseudobulbar affect
Available dosage forms:	dextromethorphan hydrobromide 20 mg/quinidine sulfate 10 mg capsules
Usual dose:	Therapy should be initiated with 1 capsule (dextromethorphan 20 mg/quinidine sulfate 10 mg) once daily for 7 days. Thereafter, the recommended dosage is 1 capsule every 12 hours. Dosage adjustments are not necessary in patients with mild to moderate renal or hepatic impairment
Approximate monthly cost: (based on AWP 2011)	\$586.80/ month
Duration of therapy:	To be determined by physician.

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Must be clinically diagnosed with pseudobulbar affect (PBA).
- Must be clinically diagnosed with amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS).
- Must be prescribed by a neurologist.
- Patients must have a baseline score of at least 13 on the Center for Neurologic Studies-Lability Scale (CNS-LS).
- Must have at least 4-7 episodes per day.

Criteria for continuation of therapy:

- Decrease in score on the CNS-LS.
- Decrease in number of episodes per day.

Caution:

- Dextromethorphan/quinidine causes dose-dependent QT prolongation. In patients at risk of QT prolongation, such as those taking other medications that prolong the QT interval, patients taking CYP3A4 inhibitors, and patients with left ventricular hypertrophy or left ventricular dysfunction, electrocardiogram (ECG) evaluation of the QT interval is advised at baseline and 3 to 4 hours after the first dose.
- Caution is advised with the concomitant use of CYP2D6 substrates

Contraindication:

- history of quinidine-, quinine-, or mefloquine-induced thrombocytopenia; a history of hepatitis, bone marrow depression, lupus-like syndrome, or hypersensitivity; a known hypersensitivity to dextromethorphan; prolonged QT interval or congenital long QT syndrome; a history suggestive of torsades de pointes; heart failure; and those with complete atrioventricular (AV) block without an implanted pacemaker or a high risk of complete AV block. Concomitant use with quinidine, quinine, mefloquine, MAOIs (or use within 14 days of stopping an MAOI), and drugs that prolong the QT interval and are metabolized by CYP2D6 (eg, thioridazine, pimozide) is also contraindicated.

Not approved if:

- Have any contraindications to the use of Nuedexta.
- Does not meet the above stated criteria.

Special considerations:

- Higher doses of 30mg dextromethorphan and 30mg quinidine. Caused dose dependent qt prolongation and torsades de pointes which is why it wasn't approved by the fda before.
- Emotional lability is common in a range of disorders, such as Alzheimer's and other dementias, the drug has only been proven safe and effective in randomized trials for patients with ALS and MS. And patients with other underlying neurologic diseases may experience other adverse reactions not described in the PI.(such as stroke or traumatic brain injury)
- Treatment effects were observed as early as the first week of treatment. Complete remission during weeks 9 through 12 was achieved in 45.6% of patients in the dextromethorphan/quinidine group compared with 21.1% in the placebo group

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 09/07/11