Commercial/Healthcare Exchange PA Criteria

Effective: April 2011

Prior Authorization: Nuedexta

Products Affected: Nuedexta (dextromethorphan hydrobromide and quinidine sulfate) oral capsules

Medication Description:
Nuedexta is an oral formulation of dextromethorphan hydrobromide USP and quinidine sulfate USP in a fixed dose combination. Dextromethorphan hydrobromide is the pharmacologically active ingredient of Nuedexta that acts on the central nervous system (CNS). Quinidine sulfate is a specific inhibitor of CYP2D6-dependent oxidative metabolism used in Nuedexta to increase the systemic bioavailability of dextromethorphan.

Nuedexta is indicated for the treatment of pseudobulbar affect (PBA). PBA occurs secondary to a variety of otherwise unrelated neurologic conditions, and is characterized by involuntary, sudden, and frequent episodes of laughing and/or crying. PBA episodes typically occur out of proportion or incongruent to the underlying emotional state. PBA is a specific condition, distinct from other types of emotional lability that may occur in patients with neurological disease or injury.

Covered Uses: treatment of pseudobulbar affect (PBA).

Exclusion Criteria:

1. Concomitantly use of other drugs containing quinidine, quinine, or mefloquine
2. Patients with a history of quinine, mefloquine or quinidine-induced thrombocytopenia, hepatitis, bone marrow depression or lupus-like syndrome
3. Patients with a known hypersensitivity to dextromethorphan (e.g. rash, hives)
4. Patients taking monoamine oxidase inhibitors (MAOIs) or in patients who have taken MAOIs within the preceding 14 days
5. Patients with a prolonged QT interval, congenital long QT syndrome or a history suggestive of torsades de pointes, and in patients with heart failure
6. Patients receiving drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine and pimozide), as effects on QT interval may be increased
7. Patients with complete atrioventricular (AV) block without implanted pacemakers, or in patients who are at high risk of complete AV block

Required Medical Information:

1. Diagnosis
2. Medical history
3. Current therapy regimen

Prescriber Restriction: Prescribed by, or in consultation with, a neurologist

Age Restrictions: 18 years of age and older

Coverage Duration: 12 months

Other Criteria:

A. Patient has a documented diagnosis of pseudobulbar affect (PBA), as defined by involuntary, sudden, and frequent episodes of laughing and/or crying.

References:

1. Product Information: NUEDEXTA oral capsules, dextromethorphan hydrobromide quinidine sulfate oral capsules. Avanir Pharmaceuticals, Inc. (per FDA), Aliso Viejo, CA, 2015.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	4/2011
2	Policy Update	New Template; Made separate QL policy; CCI P&T Review History: 4/11, 12/11, 10/12, 10/13, 10/14, 5/16, 2/17, 1/18 CCI Revision Record: 8/15, 7/16	All	12/11/2019