



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

NEXT REVIEW DATE: August 2012

ORIGINAL EFFECTIVE DATE: September 8, 2011
LAST REVIEW DATE: 9/29/11
LAST CRITERIA REVISION DATE: NA
ARCHIVE DATE:

Nuedexta™ (dextromethorphan and quinidine)

9-8-2011

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety. The guideline is not a guarantee of coverage.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational & thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available. The guideline in effect on the date of service will determine coverage."
For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Nuedexta is the first and only FDA-approved treatment for pseudobulbar affect (PBA). PBA is characterized by involuntary, sudden, and frequent episodes of laughing and/or crying that are out of proportion or incongruent to the underlying emotional state. PBA occurs as a secondary presentation to a variety of unrelated neurological conditions.

Studies that support the effectiveness of Nuedexta were performed in individuals with Multiple Sclerosis (MS) and Amyotrophic Lateral Sclerosis (ALS). Nuedexta has not been shown to be safe and effective in other types of emotional liability that can occur in Alzheimer's disease and other dementias. Spontaneous improvement of PBA is known to occur in some individuals.

Nuedexta capsules contain 20mg of Dextromethorphan Hydrobromide and 10mg of Quinidine Sulfate. Dextromethorphan, found in many cough medicines, is a sigma-1 receptor agonist and an uncompetitive NMDA receptor antagonist. Its mechanism of action as an anti-tussive agent occurs through depression of the medullary cough center, interruption of cough impulse transmission, and a reduction of the sensitivity of cough reflex. The mechanism by which Dextromethorphan exerts therapeutic effects in PBA is unknown. Quinidine is a class 1A anti-arrhythmic used in individuals with atrial fibrillation. In Nuedexta, its purpose is to inhibit metabolism of Dextromethorphan via CYP2D6, leading to higher levels plasma levels of Dextromethorphan.

Nuedexta is contraindicated in individuals with a history of Nuedexta, quinine, mefloquine or quinidine-induced thrombocytopenia, hepatitis, bone marrow depression or lupus-like syndrome. Nuedexta is also



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contraindicated in individuals with a known hypersensitivity to dextromethorphan (e.g. rash, hives). The safety and effectiveness of Nuedexta in pediatric individuals below the age of 18 have not been established.

Precertification:

Precertification* for Nuedexta is required for members with a Blue Cross Blue Shield of Arizona (BCBSAZ) retail and mail order prescription benefit. Medications requiring precertification are identified on the following list located on the Internet at <http://www.azblue.com/pdfs/medications/pharmacy/QIList.pdf>:

"Prescription Limitations and Precertification Requirements for Retail and Mail Order Prescriptions"

This list may also be requested by calling (602) 864-4273 or (800) 232-2345, ext. 4273.

Please refer to this list for other Nuedexta prescription claim limitations where applicable.

- * Precertification will not be required for certain individuals who are already receiving Nuedexta . Members having at least one BCBSAZ paid claim for Nuedexta within the three months preceding the initial effective date of this guideline will not need to obtain precertification.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.



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Criteria:

- FDA-approved dosage of Nuedexta is considered **medically necessary** for individuals 18 years of age and older for the treatment of pseudobulbar affect (PBA) characterized by involuntary, sudden, and frequent episodes of laughing and/or crying that are out of proportion or incongruent to the underlying emotional state in individuals diagnosed with amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS).

Nuedexta for all other indications not previously listed, is considered experimental or investigational based upon;

1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
2. Insufficient evidence to support improvement of the net health outcome, and
3. Insufficient evidence to support improvement of the net health outcome as much as, or more than established alternatives

History:

Date:

Activity:

Pharmacy and Therapeutics
review

8-4-2011

Adopted guideline

Director Pharmacy Mgmt review

6-1-2011

Development

Criteria Revisions:



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Nuedexta™

Resources:

Nuedexta™ package insert 10/2010
