BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES	
SECTION: DRUGS	
ORIGINAL EFFECTIVE DATE:	**9/08/11**
LAST REVIEW DATE:	**5/16/19**
LAST CRITERIA REVISION DATE:	**5/17/18**
ARCHIVE DATE:	

NUEDEXTA™ (dextromethorphan and quinidine) oral capsule

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 to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

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 and 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.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

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.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

NUEDEXTA™ (dextromethorphan and quinidine) oral capsule (cont.)

Criteria:

- **Criteria for initial therapy:** Nuedexta (dextromethorphan and quinidine) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual is 18 years of age or older

  2. A confirmed diagnosis 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

  3. There are **NO** contraindications:
     - Contraindications include:
       - Concurrent use with Quinidine, Quinine, or Mefloquine
       - History of Quinidine, Quinine, or Mefloquine induced thrombocytopenia, hepatitis, or other hypersensitivity reaction
       - Known hypersensitivity to Dextromethorphan
       - Use with a mono-amine oxidase inhibitor (MAOI) or within 14 days of stopping a MAOI
       - Prolonged QT interval, congenital long QT syndrome, history of torsades de pointes, or heart failure
       - Complete atrioventricular (AV) node block without an implanted pacemaker, or individual at high risk of complete AV block
       - Use with drugs that both prolong QT interval and are metabolized by cytochrome P450 2D6 (such as thioridazine or pimozide)

  4. Will not be used with another Dextromethorphan containing product for other medical condition

  Initial approval duration: 60 capsules per month for 6 months

- **Criteria for continuation of coverage (renewal request):** Nuedexta (dextromethorphan and quinidine) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual's condition has not worsened while on therapy
     - Worsening is defined as:
       - No change in the frequency of laughing and crying episodes that are out of proportion or incongruent to the underlying emotional state

  2. Individual has been adherent with the medication

  3. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
     - Contraindications as listed in the criteria for initial therapy section
     - Significant adverse effect such as:
       - Immune mediated drug induced thrombocytopenia
       - Hepatitis
       - Serotonin syndrome

NUEDEXTA™ (dextromethorphan and quinidine) oral capsule (cont.)

- Torsades de point-type ventricular arrhythmia

4. There are no significant interacting drugs

Renewal duration: 60 capsules per month for 12 months

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. It is a specific condition, distinct from other types of emotional lability that may occur in patients with neurological disease or injury.

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 antitussive 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 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.

Resources:

Nuedexta product information accessed 04-10-19 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=484e0918-3442-49dc-8ccf-177f1f3ee9f3

Nuedexta. Package Insert. Revised 01/2015, accessed 5/6/15; revised 01/2016, accessed 3/28/17, 3/14/18.

Nuedexta. Package Insert, 10/2010, NUE-0279-WEB-0912/ Rev. Date 08/2011; viewed on 08-25-2012.

King RR and Reiss JP: The epidemiology and pathophysiology of pseudobulbar affect and its association with neurodegeneration. Degen Neurolog Neuromusc Dis 2013;3:23-31

UpToDate: Symptom-based management of amyotrophic lateral sclerosis. Current through Mar, 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/symptom-based-management-of-amyotrophic-lateral-sclerosis?search=pseudobulbar%20affect&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.