

Pharmacy Policy

Nuedexta®

Policy Number: 9.200

Version Number: 2.0

Version Effective Date: 6/1/2021

<p>Product Applicability <input type="checkbox"/> All Plan+ Products</p>	
<p>Well Sense Health Plan</p> <p><input type="checkbox"/> New Hampshire Medicaid</p> <p><input type="checkbox"/> NH Health Protection Program</p> <p><input type="checkbox"/> _____</p>	<p>Boston Medical Center HealthNet Plan</p> <p><input type="checkbox"/> MassHealth ACO</p> <p><input type="checkbox"/> MassHealth MCO</p> <p><input checked="" type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct</p> <p><input type="checkbox"/> Senior Care Options</p> <p><input type="checkbox"/> _____</p>

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Nuedexta (dextromethorphan/quinidine)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All approved FDA indication unless otherwise excluded
Exclusion Criteria	<ol style="list-style-type: none"> 1. Current MAOI use or use of an MAOI within the last 14 days. 2. Prolonged QT interval, congenital long QT syndrome, history suggestive of torsades de pointes, or heart failure. 3. Concomitant use of drugs the both prolong QT interval and are metabolized by CYP2D6 (e.g. thioridazine, pimozide).
Required Medical Information	<p>Documentation of the following:</p> <ol style="list-style-type: none"> 1. A diagnosis of pseudobulbar affect; AND

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	2. Provider attestation that a diagnosis of depression has been ruled out or is currently managed
Age Restrictions	None
Prescriber Restriction	Prescribed by or in collaboration with a neurologist or psychiatrist
Coverage Duration	12 months
Other criteria	Reauthorization: 1. Clinically significant reduction in symptom severity and frequency.

Clinical Background Information and References

1. Product Information. NUEDEXTA® (dextromethorphan hydrobromide and quinidine sulfate); Avanir Pharmaceuticals, Inc, Aliso Viejo, CA Rev. Date 08/2011. Revised 01/2015
2. Cummings, J, Pseudobulbar Affect: Expert Insights April 2013
3. Facts and Comparisons, **Wolters Kluwer Health, Inc. 2013 accessed June 2013**
4. Piro EP, Rooks BR, Cummings J, et al. Dextromethorphan plus ultra-low-dose quinidine reduces pseudobulbar affect. *Ann Neurol.* 2010; 68:693-702.
5. Panitch HS, Thisted RA, Smith RA, et al. Randomized, controlled trial of dextromethorphan/quinidine for pseudobulbar affect in multiple sclerosis. *Ann Neurol.* 2006; 59:780-787.
6. Martin Paspe Cruz, PharmD, CGP, BCPP. Nuedexta for the Treatment of Pseudobulbar Affect. P T. 2013 June; 38 (6): 325-328.
7. Piro EP. Review of Dextromethorphan 20 mg/Quinidine 10 mg (NUEDEXTA®) for Pseudobulbar Affect. *Neurol Ther.* 2014 Jun 17;3(1):15-28. doi: 10.1007/s40120-014-0018-5. eCollection 2014.
8. Galvez-Jimenez N. Symptom-based management of amyotrophic lateral sclerosis. Last updated Feb 07,2018. UpToDate®. Available at www.uptodate.com. Accessed June 14, 2018.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.042 Nuedexta Policy retired, new policy created	1/1/2021	P&T Committee
2/11/2021	P&T annual review. Added exclusion criteria. Removed requirements for	6/1/2021	P&T Committee

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Policy Revisions History

	pseudobulbar affect to be associated with specific conditions.		
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Next Review Date

2/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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