Original Effective Date: 04/01/2018
Current Effective Date: 07/04/2024
Last P&T Approval/Version: 04/24/2024
Next Review Due By: 04/2025
Policy Number: C12971-C

Nuedexta (dextromethorphan/quinidine)

PRODUCTS AFFECTED

Nuedexta (dextromethorphan/quinidine)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This 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 Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Pseudobulbar affect (PBA)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. PSEUDOBULBAR AFFECT (PBA):
1. Documentation of a diagnosis of pseudobulbar affect (PBA) secondary to a neurological condition (Lou Gehrig's disease/ Amyotrophic lateral sclerosis [ALS], multiple sclerosis [MS], stroke, traumatic brain injury [TBI]) defined by involuntary, sudden, and frequent episodes of

laughing and/or crying, typically occurring out of proportion or incongruent to the underlying emotional state
AND

2. Documentation of a Center for Neurologic Study-Lability Scale (CNS-LS) baseline score of at least 13 (see Appendix)
AND
3. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Nuedexta (dextromethorphan hydrobromide and quinidine sulfate) include: Concomitant use with quinidine, quinine, or mefloquine, Patients with a history of quinidine, quinine or mefloquine-induced thrombocytopenia, hepatitis, or other hypersensitivity reactions, Patients with known hypersensitivity to dextromethorphan, Use with an MAOI or within 14 days of stopping an MAOI, Prolonged QT interval, congenital long QT syndrome, history suggestive of torsades de pointes, or heart failure, Complete atrioventricular (AV) block without implanted pacemaker, or patients at high risk of complete AV block, Concomitant use with drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine or pimozide).]

CONTINUATION OF THERAPY:

A. PSEUDOBULBAR AFFECT (PBA):

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms
AND
4. Prescriber attests to reassessing member periodically for medical necessity of continued treatment, as spontaneous improvement of PBA occurs in some patients.

DURATION OF APPROVAL:

Initial authorization: 3 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a neurologist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

Starting dose: 1 capsule daily for 7 days
Maintenance dose: 2 capsules per day (1 every 12 hours)

PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Oral

DRUG CLASS:
Pseudobulbar Affect Agent Combinations

FDA-APPROVED USES:
Indicated for the treatment of pseudobulbar affect (PBA)

NOTE: 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.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
CNS-LS evaluation:
Using the scale below, please write the number that describes the degree to which each item applies to you DURING THE PAST WEEK. Write only 1 number for each item.

Applies never	Applies rarely	Applies occasionally	Applies frequently	Applies most of the time
1	2	3	4	5

Assessment Question	Answer
1. There are times when I feel fine 1 minute, and then I'll become tearful the next over something small or for no reason at all.	
2. Others have told me that I seem to become amused very easily of that I seem to become amused about things that really aren't funny.	
3. I find myself crying very easily	
4. I find that even when I try to control my laughter, I am often unable to do so.	
5. There are times when I won't be thinking of anything happy or funny at all, but then I'll suddenly be overcome by funny or happy thoughts.	
6. I find that even when I try to control my crying, I am often unable to do so.	
7. I find that I am easily overcome by laughter.	

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Nuedexta (dextromethorphan hydrobromide and quinidine sulfate) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Nuedexta (dextromethorphan hydrobromide and quinidine sulfate) include: Concomitant use with quinidine, quinine, or mefloquine, Patients with a history of quinidine, quinine or mefloquine-induced thrombocytopenia, hepatitis, or other hypersensitivity reactions, Patients with known hypersensitivity to dextromethorphan, Use with an MAOI or within 14 days of stopping an MAOI, Prolonged QT interval, congenital long QT syndrome, history suggestive of torsades de pointes, or heart failure, Complete atrioventricular (AV) block without implanted pacemaker, or patients at high risk of complete AV block, Concomitant use with drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine or pimozide).

OTHER SPECIAL CONSIDERATIONS:
This is the only FDA approved drug for PBA.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Nuedexta CAPS 20-10MG

REFERENCES

1. Nuedexta (dextromethorphan/quinidine) [package insert]. Aliso Viejo, CA: Avanir Pharmaceuticals, Inc; December 2022.
2. Colamonico J, Formella A, Bradley W.Pseudobulbar Affect: burden of illness in the U.S.A. Adv Ther. 2012 Sep;29(9):775-98. Doi: 10.1007/s12325-012-0043-7.
3. Moore SR, Gresham LS, Bromberg MB, Kasarkis EJ, Smith RA. A self report measure of affective lability. J Neurol Neurosurg Psychiatry. 1997;63(1):89-93
4. Smith RA, Berg JE, Pope LE, Callahan JD, Wynn D, Thisted RA. Validation of the CNS emotional lability scale for pseudobulbar affect (pathological laughing and crying) in multiple sclerosis patients. Mult Scler. 2004;10(6):679-685.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information References	Q2 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity Appendix Contraindications/Exclusions/Discontinuation References	Q2 2023
REVISION- Notable revisions: Prescriber Requirements	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file