Nuedexta (dextromethorphan/quinidine)
Policy Number: C12971-C

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DUE BY OR BEFORE
4/1/2018	2/17/2021	4/26/2022
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
NA	RxPA	Q2 2021 20210428C12971-C

PRODUCTS AFFECTED:
Nuedexta (dextromethorphan/quinidine)

DRUG CLASS:
Pseudobulbar Affect Agent Combinations

ROUTE OF ADMINISTRATION:
Oral

PLACE OF SERVICE:
Retail Pharmacy
The recommendation is that medications in this policy will be for pharmacy benefit coverage and patient self-administered

AVAILABLE DOSAGE FORMS:
Nuedexta Cap 20-10MG

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

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS:
pseudobulbar affect (PBA)

REQUIRED MEDICAL INFORMATION:
A. PSEUFOBULBAR AFFECT (PBA):

1. Documentation of a diagnosis of PBA secondary to a neurological condition (ALS, MS, stroke, 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 appendix1)
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).]

DURATION OF APPROVAL:
Initial authorization: 3 months, Continuation of Therapy: for up to 12 months

QUANTITY:
2 capsules per day (1 every 12 hours)

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with neurologist

AGE RESTRICTIONS:
18 years of age and older

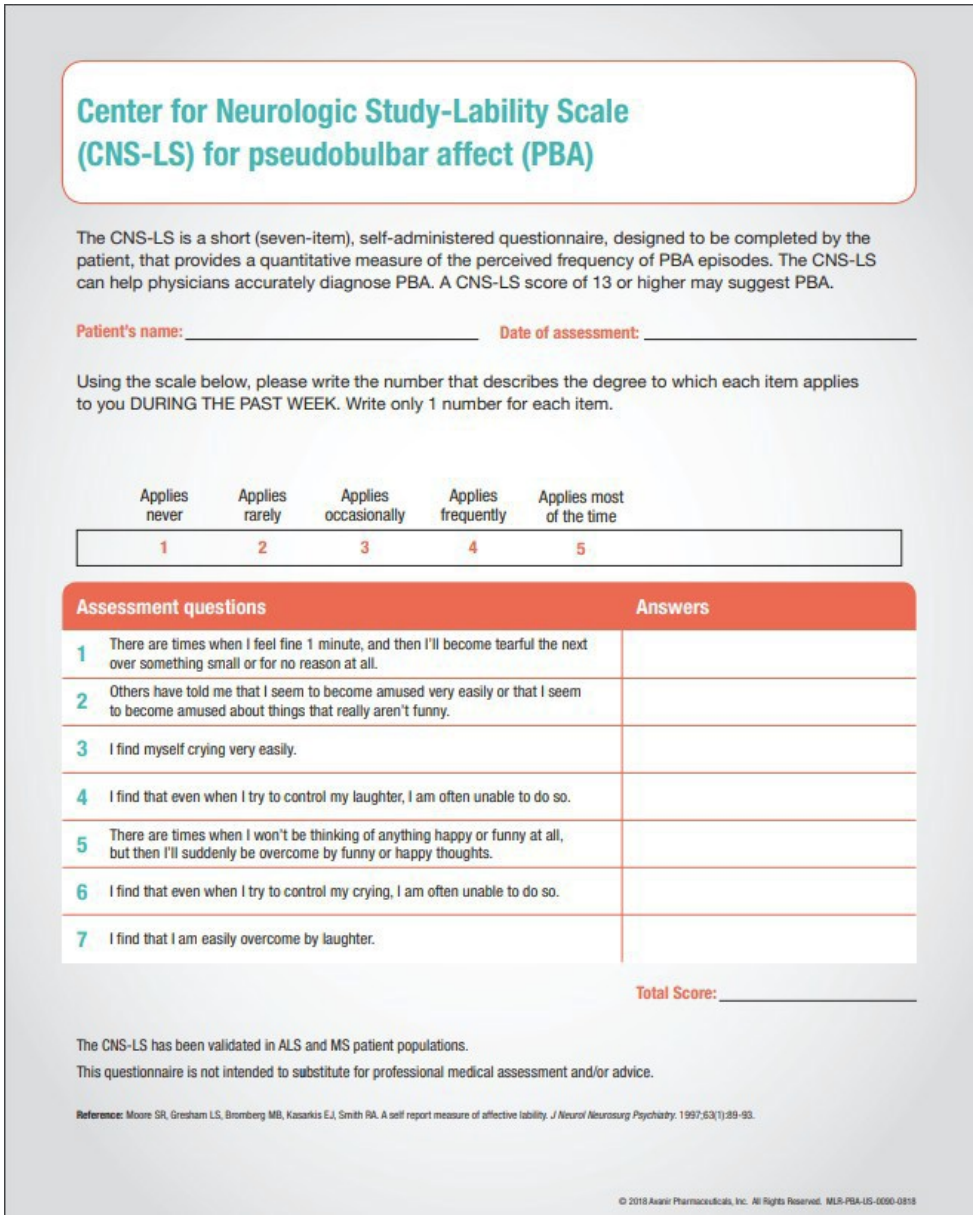
CONTINUATION OF THERAPY:
A. PSEUDOBULBAR AFFECT(PBA):
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation (documentation required)
AND
2. Documentation of no 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 for medical necessity of continued treatment, as spontaneous improvement of PBA occurs in some patients.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Nuedexta are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindicated in patients taking MAOI's or who have taken MAOI in last 14 days. Contraindicated in patients with a prolonged QT interval, congenital long QT syndrome or a history suggestive of torsades de pointes, and in patients with heart failure. Contraindicated in patients with complete atrioventricular (AV) block without implanted pacemakers, or in patients who are at high risk of complete AV block. Should not be used concomitantly with other drugs containing quinidine, quinine, or mefloquine

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

BACKGROUND:
None

APPENDIX:
CNS-LS evaluation: https://www.nuedextahcp.com/sites/default/files/pdf/CNS_LS_Questionnaire.pdf



Center for Neurologic Study-Lability Scale (CNS-LS) for pseudobulbar affect (PBA)

The CNS-LS is a short (seven-item), self-administered questionnaire, designed to be completed by the patient, that provides a quantitative measure of the perceived frequency of PBA episodes. The CNS-LS can help physicians accurately diagnose PBA. A CNS-LS score of 13 or higher may suggest PBA.

Patient's name: _____ Date of assessment: _____

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 questions		Answers
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 or 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.	

Total Score: _____

The CNS-LS has been validated in ALS and MS patient populations.

This questionnaire is not intended to substitute for professional medical assessment and/or advice.

Reference: Moore SR, Gresham LS, Bromberg MB, Kasarskis EJ, Smith RA. A self report measure of affective lability. *J Neurol Neurosurg Psychiatry*. 1997;63(1):89-93.

REFERENCES:

1. Nuedexta (dextromethorphan/quinidine) [package insert]. Aliso Viejo, CA: Avanir Pharmaceuticals, Inc; June 2019
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.