

ALASKA MEDICAID
Prior Authorization Criteria

Nuedexta®
(dextromethorphan/ quinidine)

FDA INDICATIONS AND USAGE¹

Nuedexta® is a combination of dextromethorphan hydrobromide and quinidine sulfate indicated for the treatment of pseudobulbar affect (PBA). PBA is characterized by involuntary, sudden, and frequent episodes of laughing or crying secondary to unrelated neurologic conditions.

APPROVAL CRITERIA^{1,2,3}

1. Patient is 18 years of age or older **AND**;
2. Patient has a confirmed diagnosis of pseudobulbar affect associated with multiple sclerosis, amyotrophic lateral sclerosis, stroke, Parkinson's disease, Alzheimer's disease or traumatic brain injury **AND**;
3. Being prescribed by or in consultation with a neurologist or psychiatrist **AND**;
4. Patient has tried and failed at a therapeutic dose of one SSRI (I.E. fluoxetine) and one TCA (I.E. amitriptyline) or has a contraindication to use.
5. Patient must have a baseline score of at least 13 on the Center for Neurologic Studies-ability scale.

DENIAL CRITERIA^{1,2,3}

1. Patient is less than 18 years of age **OR**;
2. Patient does not have a confirmed diagnosis of pseudobulbar affect associated with multiple sclerosis, amyotrophic lateral sclerosis, stroke, or traumatic brain injury **OR**;
3. Medication is not being prescribed by or in consultation with a neurologist or psychiatrist **OR**;
4. Patient has not tried and failed at a therapeutic dose of one SSRI (I.E. fluoxetine) and one TCA (I.E. amitriptyline) or has a contraindication to use **OR**;
5. Patient is taking quinidine, quinine, mefloquine, or other medications that prolong the QT interval and metabolized by CYP2D6 **OR**;
6. Concomitant use of MAOI with in the last 14 days **OR**;
7. Patient has prolonged QT interval, heart failure, or complete atrioventricular block without an implanted pacemaker.

CAUTIONS¹

- Patients should be advised that certain prescription and OTC medications have significant interactions when taken concomitantly.
- Thrombocytopenia, hepatitis, and other hypersensitivity reactions have occurred.

DURATION OF APPROVAL

Nuedexta® Criteria
Version: 1
Original: 12/10/2018
Approval: 1/18/2019
Effective: 3/11/19

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- Initial Approval: up to 3 months
- Re-approval: up to 1 year with documentation of decreased laughing or crying episodes from the baseline.

QUANTITY LIMITS

- 60 capsules per month
- Starting dose is 1 capsule daily for 7 days, then 1 capsule every 12 hours thereafter.

REFERENCES / FOOTNOTES:

1. Nuedexta® [Package Insert]; Avanir Pharmaceuticals, Inc., Aliso Viejo, CA. January 2015. Accessed at: https://www.nuedexta.com/sites/default/files/Prescribing_Information.pdf. Accessed on: December 10, 2018.
2. Piro EP, Rooks BR, Cummings J, et al. Dextromethorphan plus ultra-low-dose quinidine reduces pseudobulbar affect. *Ann Neurol*. 2010; 68:693-702.
3. Jack J. Chen, PharmD, BCPS, BCGP. Pharmacotherapeutic Management of Pseudobulbar Affect. *Am J Managed Care*. 2017;23. Accessed at: <https://www.ajmc.com/journals/supplement/2017/pseudobulbar-affect-considerations-for-managed-care-professionals/pharmacotherapeutic-management-of-pseudobulbar-affect>. Accessed on: December 10, 2018.