Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.

Policies submitted without this form will not be considered for review.

Plan: Aetna Better Health	**Submission Date:** 9/2020
Policy Number:	**Effective Date:** 12/1/2020 **Revision Date:** 8/2020
Policy Name: Nuedexta	
Type of Submission – Check all that apply: ☐ **New Policy** ☐ **Annual Review – No Revisions** **X Revised Policy**	
***All revisions to the policy must be highlighted using track changes throughout the document.** **Please provide any clarifying information for the policy below:** Updated criteria per P&T annual review. Thank you.	
Name of Authorized Individual (Please type or print): **Natalie Nkurunziza, Pharm.D.**	**Signature of Authorized Individual:** 

Last Review: 8/2020
Last PARP Approval: 12/2019
Current PARP Approval: 10/2020

AETNA BETTER HEALTH®

Non-Formulary Prior Authorization guideline for Nuedexta (Non-PDL)

Authorization guidelines

May be authorized when all the following criteria are met:

A. Member is 18 years of age or older
B. Medication is prescribed by, or in consultation with, a specialist (for example, a psychiatrist, psychologist, neuropsychologist, or neurologist)
C. Diagnosis of pseudobulbar affect (PBA)
D. Documentation that member has at least ONE underlying neurologic condition associated with PBA
E. Cognitive assessment to evaluate for the presence of pseudobulbar affect (PBA) (for example, Center for Neurologic Study-Lability Scale (CNS-LS) ≥ 13, The Pathological Laughter and Crying Scale (PLACS) ≥ 13)
F. Member does not have any contraindication to therapy (for example, QT prolongation, Atrioventricular (AV) block or (monoamine oxidase inhibitor (MAOI) therapy in the previous 14 days)
G. Member has tried and failed selective serotonin reuptake inhibitors (SSRIs), or tricyclic antidepressants (TCAs)
H. Dose adjustments to desipramine, paroxetine, and digoxin will be made if co-administered with Nuedexta

Approval Duration

Initial Approval: 3 months

Renewal: 1 year

Criterion: decreased frequency of pseudobulbar affect (PBA) episodes.

Quantity Level Limit: 2 capsules per day

Nuedexta is NOT covered for members with the following criteria:

- Use not approved by the FDA; **AND**
- The use is unapproved and not supported by the literature or evidence as an accepted off-label use.

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Medically Necessary — A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

Determination of Medical Necessity for covered care and services, whether made on a Prior Authorization, Concurrent Review, Retrospective Review, or exception basis, must be documented in writing.

The determination is based on medical information provided by the Member, the Member's family/caretaker and the Primary Care Practitioner, as well as any other Providers, programs, agencies that have evaluated the Member.

All such determinations must be made by qualified and trained Health Care Providers. A Health Care Provider who makes such determinations of Medical Necessity is not considered to be providing a health care service under this Agreement.

References:

1. Nuedexta® (dextromethorphan hybromide and quinidine sulfate). Avanir Pharmaceuticals, Inc. Aliso Viejo, CA. June 2019. https://www.nuedexta.com/sites/default/files/pdfs/Prescribing_Information.pdf. Accessed April 30, 2020.
2. Ahmed A and Simmons Z. Pseudobulbar affect: prevalence and management. Therapeutics and Clinical Risk Management 2013;9:482-489.
3. Brook BR, Crumacker D, Fellus J, et al. PRISM: A novel research tool to assess the prevalence of pseudobulbar affect symptoms across neurological conditions. PLOS one.2013;8(8):e72232
4. Hammond FM, Alexnader DN, Cutler AJ, et al. PRISM II: an open-label study to assess effectiveness of dextromethorpahan/quinidine for pseudobulbar

affect in patients with dementia, stroke or traumatic brain injury. BMD Neurology. 2016;16(89).
5. Lapchak P. Neuronal Dysregulation in Stroke-Associated Pseudobulbar Affect (PBA): Diagnostic scales and current treatment options. J Neurol Neurophysiol. 2016;6(5):323.
6. Miden SL, Feintein A, Kalk RS, et al. Evidence-based guideline: Assessment and management of psychiatric disorders in individuals with MS. Neurology. 2014;82(2):174-181.
7. Robinson RG, Parikh RM, and Lipsey JR, et al. Pathological laughing and crying following stroke: validation of a measurement scale and a double-blind treatment study. Am J Psychiatry. 1993;150(2): 286-293.
8. Woodard T.J, Charles K, et al. Review of the Diagnosis and Management of Pseudobulbar Affect. US Pharm. 2017;42(11)31-35.
9. Demier TL, Chen JJ. Pseudobulbar Affect: Considerations for Managed Care Professionals. The American Journal of Managed Care, 2017;23:-S0.
10. AJMC Managed Markets Network, Pharmacotherapeutic Management of Pseudobulbar Affect, December 2017; available from https://www.ajmc.com/journals/supplement/2017/pseudobulbar-affect-considerations-for-managed-care-professionals/pharmacotherapeutic-management-of-pseudobulbar-affect?p=2. Accessed April 30, 2020.