UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Nuedexta

Program	Prior Authorization
Medication	Nuedexta (dextromethorphan HBr/quinidine)
Issue Date	6/2011
Pharmacy and Therapeutics Approval Date	10/2017
Effective Date	11/2017

1. Background:

Indications

Pseudobulbar Affect (PBA) [1]
Is indicated for the treatment of pseudobulbar affect (PBA). 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. Studies to support the effectiveness of Nuedexta were performed in patients with amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS). Neudexta has not been shown to be safe and effective in other types of emotional lability that can commonly occur, for example, in Alzheimer's disease and other dementias.

2. Coverage Criteria:

A. Authorization

1. Diagnosis of pseudobulbar affect (PBA) [1,A]

Authorization will be issued for 12 months.

3. Endnotes

A. A diagnosis code specifically for PBA has been requested and is anticipated by early 2012.
B. Efficacy measures for PBA treatment primarily consist of assessment of episode reduction and episode intensity reduction. For the purpose of clinical trials, the Center for Neurologic Study-Lability Scale (CNS-LS) has been used. [3] The CNS-LS is a short (seven-item), self-administered questionnaire, designed to be completed by the patient,

and 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. The CNS-LS has been validated in ALS and MS patient population. [4]

C. The CNS-LS provides the same method for measuring PBA due to other neurological conditions as PBA due to ALS/MS. It is reasonable to require the validated CNS-LS tool for diagnosing PBA in the populations for which this scale has not been validated. If a patient suffers from dementia (eg, Alzheimer's disease), a caregiver could complete the questionnaire. [8]
D. Patients should be evaluated for Nuedexta benefit after the initial 3 months of treatment. [8]

4. References

1. Nuedexta (dextromethorphan HBr and quinidine) capsules [package insert]. Aliso Viejo, CA: Avanir Pharmaceuticals, Inc; October 2010.
2. Miller RG, Jackson CE, Kasarskis EJ, et al. Practice Parameter update: The care of the patient with amylotrophic lateral sclerosis: Multidisciplinary care, symptom management, and cognitive/behavioral impairment (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. October 13, 2009;72:1227-1233
3. Arciniegas DB, Lauterbach EC, Anderson KE, et al. The differential diagnosis of pseudobulbar affect (PBA). Distinguishing PBA among disorders of mood and affect. Proceedings of a roundtable meeting. CNS Spectr. 2005 May;10(5):1-14; quiz 15-6.
4. Center for Neurologic Study-Lability Scale (CNS-LS) for pseudobulbar affect (PBA). Available at: www.nuedexta.com/pdf/CNS%20LS%20Questionnaire.pdf. Accessed June 14, 2011.
5. Pioro EP, Brooks BR, Cummings JR et al. Dextromethorphan plus ultra low-dose quinidine reduces pseudobulbar affect. Ann Neurol. 2010 Nov;68(5):693-702.
6. Wortzel HS, Oster TJ, Anderson CA, Arciniegas DB. Pathological laughing and crying: epidemiology, pathophysiology and treatment. CNS Drugs. 2008;22(7):531-45. Review.
7. USP. Final Report, summary of methodology and approach March 11, 2011. Available at: http://www.usp.org/pdf/EN/mmg/2011-03-11MethodologyAndApproach.pdf Accessed June 28, 2011.
8. Per clinical consultation with neurologist, September 8, 2011.

Program	Prior Authorization- Nuedexta (dextromethorphan HBr/quinidine)
Change Control	
Date	Change
June 2011	New drug policy
August 2011	Requirement that the prescriber is a Nuerologist Initial authorization period changed to 6 months

	Reauthorization criteria requires documentation of the benefit of Nuedexta therapy
June 2012	Annual Review
June 2013	Converted policy to new UHC enterprise wide formatting. Removed requirement that the patient has underlying ALS or MS Decreased initial authorization to 3 months
Dec 2015	Annual Review
Nov 2016	Updated policy template. Removed extra sections not related to clinical criteria.
March 2017	Updated policy template
September 2017	Removed prescriber check and updated authorization duration to 12 months. Removed reauthorization criteria to allow for Dx to Rx implementation.