PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

NUEDEXTA
(dextromethorphan hydrobromide/quinidine sulfate)

Status: CVS Caremark Criteria ***Ref# 870 -A***
Type: Initial Prior Authorization ***Ref# MDC-2 599-A***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated*

FDA-APPROVED INDICATIONS
Nuedexta 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. PBA is a specific condition, distinct from other types of emotional lability that may occur in patients with neurological disease or injury.

COVERAGE CRITERIA (870-A and MDC-2 599-A)
The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has a diagnosis of pseudobulbar affect (PBA)

RATIONALE
These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Nuedexta 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. PBA is a specific condition, distinct from other types of emotional lability that may occur in patients with neurological disease or injury.

Nuedexta contains quinidine, and should not be used concomitantly with other drugs containing quinidine, quinine, or mefloquine. Nuedexta is contraindicated in patients taking monoamine oxidase inhibitors (MAOIs) or in patients who have taken MAOIs within the preceding 14 days, due to the risk of serious and possibly fatal drug interactions, including serotonin syndrome.

Nuedexta is 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. Nuedexta is contraindicated in patients receiving drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine and pimozide), as effects on QT interval may be increased. Nuedexta is contraindicated in patients with complete atrioventricular (AV) block without implanted pacemakers, or in patients who are at high risk of complete AV block.

Nuedexta has not been systematically studied for its potential for abuse, tolerance, or physical dependence. However, cases of dextromethorphan abuse have been reported. Metabolism of dextromethorphan is inhibited by quinidine, such that adverse effects of overdose due to Nuedexta might be more severe or more persistent compared to overdose of dextromethorphan alone. While therapeutic doses of quinidine for treatment of cardiac arrhythmia or malaria are generally 10-fold or more, higher than the dose of quinidine in Nuedexta, potentially fatal cardiac arrhythmia, including torsades de pointes, can occur at quinidine exposures that are possible from Nuedexta overdose.

REFERENCES

1. Nuedexta [package insert]. Aliso Viejo, CA: Avanir Pharmaceuticals, Inc.; January 2016.
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4. Pioro E, Brooks B, Cummings J, et al. Dextromethorphan Plus Ultra Low-Dose Quinidine Reduces Pseudobulbar Affect. *Ann Neurol* 2010:68:693-702.
5. Miller R, Jackson C, Kasarskis E, et al. Practice Parameter update: The care of the patient with amyotrophic lateral sclerosis: Multidisciplinary care, symptom management, and cognitive/behavioral impairment (an evidence-based review): Report of the Subcommittee of the American Academy of Neurology Quality Standards. *Neurology* 2009;73:1227–1233.
6. Rosen H. Dextromethorphan/Quinidine sulfate (Zenvia) for Pseudobulbar Affect. *Drugs Today (Barc)* 2008;44(9):661–668.
7. Shaibani AI. Efficacy and safety of dextromethorphan/quinidine at two dosage levels for diabetic neuropathic pain: a double-blind, placebo-controlled, multicenter study. *Pain Med* 2012 Feb*;* 13(2): 243-54.

Written by: UM Development (TM)
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MDC-2 559-A: (MS) 09/2011, 08/2012, (SE) 04/2013, (SE) 07/2013 (removed quantity limits), 08/2013; (MS) 08/2014, (LN) 04/2015 (Added denial Reasons); (MS) 08/2015, (SE) 06/2016 (created separate Med D); (MS) 08/2016 (removed safety question), (SE/AJ) 08/2017
(SE/AH) 08/2018 (combined documents - no clinical changes)
Reviewed: Medical Affairs 870-A: (KP) 12/2010, 09/2011; (DC) 08/2012, (LMS) 08/2013; (SS) 08/2014; (LB) 08/2015; (ME) 08/2016, (JG) 08/2017
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External Review: 02/2011, 12/2011, 02/2013, 02/2014, 12/2014, 12/2015, 12/2016, 12/2017, 12/2018

CRITERIA FOR APPROVAL (870-A and MDC-2 599-A)

1	Does the patient have a diagnosis of pseudobulbar affect (PBA)?	Yes	No

Mapping Instructions (870-A)			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Approve, 36 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have pseudobulbar affect. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]

Guidelines for Approval (MDC-2 599-A)	
Duration of Approval	**12 Months**
Set 1	
Yes to question(s)	**No to question(s)**
1	None

Mapping Instructions (MDC-2 599-A)			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Approve, 12 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have pseudobulbar affect. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]