PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

NUEDEXTA
(dextromethorphan hydrobromide/quinidine sulfate)

Status: CVS Caremark Criteria ***Ref # 870-A***
Type: Initial Prior Authorization ***Ref # 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. OTC products are not included 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

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

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.

REFERENCES

1. Nuedexta [package insert]. Aliso Viejo, CA: Avanir Pharmaceuticals, Inc.; June 2019.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed July 2019.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed July 2019.

Written by:	UM Development (TM)
Date Written:	12/2010
Revised:	870-A: (MS) 09/2011, 08/2012; (PL) 10/2012 (extended duration), (SE) 08/2013; (MS) 08/2014, 08/2015, 08/2016 (removed safety question), (SE/AJ) 08/2017 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); (DS) 08/2019 (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 Medical Affairs MDC-2 599-A: (KP) 12/2010, 09/2011; (DC) 08/2012, (DR) 05/2013, (LMS) 07/2013, 08/2013; (SS) 08/2014; (LB) 08/2015; (ME) 08/2016, (JG) 08/2017; (CHART) 08/29/19 External Review: 02/2011, 12/2011, 02/2013, 02/2014, 12/2014, 12/2015, 12/2016, 12/2017, 12/2018, 12/2019

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

Mapping Instructions (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]