Reference number(s)
870-A, 599-A

Initial Prior Authorization Nuedexta

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Nuedexta	dextromethorphan hydrobromide/quinidine sulfate

Indications

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

Pseudobulbar Affect (PBA)

Authorization may be granted when the patient has a diagnosis of pseudobulbar affect (PBA).

Continuation of Therapy

Pseudobulbar Affect (PBA)

Authorization may be granted when the patient has a diagnosis of pseudobulbar affect (PBA) when the following criteria is met:

- The patient has achieved or maintained a decrease in PBA episodes since starting the requested drug.

Duration of Approval (DOA)

- 870-A: Initial therapy DOA: 4 months; Continuation of therapy DOA: 36 months
- 599-A: Initial therapy DOA: 4 months; Continuation of therapy DOA: 12 months

References

1. Nuedexta [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; December 2022.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed February 21, 2025.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 02/21/2025).
4. Hammond FM, Alexander DN, Cutler AJ, et. Al. PRISM II: An open-label study to assess effectiveness of dextromethorphan/quinidine for pseudobulbar affect in patients with dementia, stroke or traumatic brain injury. BMC Neurol. 2016;16:89.

Document History

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); (NZ) 08/2020 (no clinical changes), 03/2021 (no clinical changes); (PM) 04/2022 (no clinical changes); (DFW) 03/2023 (added COT and decreased initial DOA to 4 months); (NS) 04/2024 (no clinical changes); (ASA) 03/2025 (no clinical changes)

Reference number(s)
870-A, 599-A

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; (CHART) 08/29/19, 08/27/20, 03/31/21, 03/30/2023, 03/28/2024
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, (CHART) 08/27/20; (CHART) 03/31/21, 03/30/2023, 03/28/2024, 03/27/2025

External Review: 02/2011, 12/2011, 02/2013, 02/2014, 12/2014, 12/2015, 12/2016, 12/2017, 12/2018, 12/2019, 12/2020, 06/2021, 06/2022, 06/2023, 06/2024, 06/2025

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of pseudobulbar affect (PBA)? [If Yes, then go to 2. If No, then no further questions.]	Yes	No
2	Is this request for continuation of therapy? [If Yes, then go to 3. If No, then no further questions.]	Yes	No
3	Has the patient achieved or maintained a decrease in pseudobulbar affect (PBA) episodes since starting the requested drug? [No further questions]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for pseudobulbar affect (PBA). Your plan does not cover the drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
2.	Go to 3	Approve, 4 Months	

3.	Approve, 36 Months	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation: Efficacy]