

# 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.