Effective Date: 9/2017
Revised: 2/2019, 06/2020 Reviewed: 9/2017, 12/2018, 2/2019, 6/2020, 3/2021, 3/2022, 3/2023, 4/2024, 4/2025 Scope: Medicaid

NUEDEXTA (dextromethorphan hydrobromide/quinidine sulfate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
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.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR APPROVAL

An authorization may be granted when the following criteria are met:

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

III. CONTINUATION OF THERAPY

- The patient has documentation of positive clinical response to therapy.

IV. COVERAGE DURATION

- 12 months (initial and renewal)

V. REFERENCES

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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.

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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.

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