Helpful Reimbursement Reminders for NUEDEXTA®

(dextromethorphan HBr and quinidine sulfate)

NUEDEXTA® is the first and only FDA-approved treatment for pseudobulbar affect (PBA)

PBA occurs secondary to a variety of otherwise unrelated neurologic conditions or brain injury 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 neurologic disease or injury.[1]

While NUEDEXTA is covered for most patients,[2] a *Prior Authorization (PA) may be required**

Each health plan will determine the Prior Authorization criteria for its formulary. The following are common types of information requested to ensure that NUEDEXTA is being used appropriately and safely:

- ✓ Documentation of primary diagnosis of PBA: ICD-10-CM diagnosis code: F48.2†
- ✓ Documentation of underlying conditions in which PBA may occur
- ✓ Documentation that NUEDEXTA is not contraindicated for the patient; please refer to Important Safety Information included here
- ✓ Medical or clinical history document

For Reauthorization:
Usually at the start of the year, documentation of symptom improvement and/or improvement of CNS-LS scores may be required.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Quinidine and Related Drugs: NUEDEXTA contains quinidine, and should not be used concomitantly with other drugs containing quinidine, quinine, or mefloquine.

Hypersensitivity: NUEDEXTA is contraindicated in patients with a history of NUEDEXTA-, quinine-, mefloquine-, or quinidine-induced thrombocytopenia, hepatitis, bone-marrow depression, lupus-like syndrome, or known hypersensitivity to dextromethorphan (eg, rash, hives).

MAOIs: 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. Allow at least 14 days after stopping NUEDEXTA before starting an MAOI.

Cardiovascular: NUEDEXTA is contraindicated in patients with a prolonged QT interval, congenital long QT syndrome, history suggestive of torsades de pointes, heart failure, patients receiving drugs that both prolong QT interval and are metabolized by CYP2D6 (eg, thioridazine and pimozide), patients with complete atrioventricular (AV) block without implanted pacemaker, or at high risk of complete AV block.

GETTING STARTED

Log in to an existing account or create a free account on CoverMyMeds.com to seamlessly submit, track, and manage PA requests.

Call 1-855-4NUEDEX (1-855-468-3339) or call your reimbursement manager Monday through Friday, 8 AM to 8 PM (EST).

Ask your representative for a co-pay card for commercially insured patients‡

Please Note: NUEDEXTA is APPROVED to treat PBA in patients with a history of certain underlying neurologic conditions; however, it is NOT APPROVED to treat the underlying neurologic condition itself. Underlying neurologic conditions may include, but are not limited to, stroke, dementia, traumatic brain injury (TBI), Parkinson's disease (PD), amyotrophic lateral sclerosis (ALS), or multiple sclerosis (MS).

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS:

Thrombocytopenia and Other Hypersensitivity Reactions: Quinidine can cause immune-mediated thrombocytopenia that can be severe or fatal. Non-specific symptoms, such as lightheadedness, chills, fever, nausea, and vomiting, can precede or occur with thrombocytopenia. NUEDEXTA should be discontinued immediately if thrombocytopenia occurs.

Hepatotoxicity: Hepatitis, including granulomatous hepatitis, has been reported in patients receiving quinidine, generally during the first few weeks of therapy. Discontinue immediately if this occurs.

Cardiac Effects: NUEDEXTA causes dose-dependent QTc prolongation. QT prolongation can cause torsades de pointes–type ventricular tachycardia, with the risk increasing as the degree of prolongation increases. When initiating NUEDEXTA in patients at risk for QT prolongation and torsades de pointes, electrocardiographic (ECG) evaluation of QT interval should be conducted at baseline and 3 to 4 hours after the first dose. Some risk factors include use with CYP3A4 inhibitors or drugs that prolong QT interval, electrolyte abnormalities, bradycardia, or left ventricular hypertrophy or dysfunction. If patients taking NUEDEXTA experience symptoms that could indicate the occurrence of cardiac arrhythmias (eg, syncope or palpitations), NUEDEXTA should be discontinued, and the patient further evaluated.

Concomitant Use of CYP2D6 Substrates: NUEDEXTA inhibits CYP2D6 and may interact with other drugs metabolized by CYP2D6. Adjust dose of CYP2D6 substrates as needed.

Dizziness: NUEDEXTA may cause dizziness. Take precautions to reduce the risk of falls.

Serotonin Syndrome: Use of NUEDEXTA with selective serotonin reuptake inhibitors (SSRIs) or tricyclic antidepressants increases the risk of "serotonin syndrome."

Anticholinergic Effects of Quinidine: Monitor for worsening in myasthenia gravis.

ADVERSE REACTIONS:

The most common adverse reactions (incidence of ≥ 3% and two-fold greater than placebo) in patients taking NUEDEXTA are diarrhea, dizziness, cough, vomiting, asthenia, peripheral edema, urinary tract infection, influenza, increased gamma-glutamyltransferase, and flatulence.

These are not all the risks from use of NUEDEXTA. Please see Full Prescribing Information.

* Confirm PA requirements by calling the patient's insurance provider. Meeting the PA requirements does not guarantee approval or payment by payer.

† For your reference only. ICD-10-CM codes submitted to health plans/payers must be determined by provider and accurately describe the diagnosis of the patient.

‡ Restrictions apply. Those eligible for any state or federally funded prescription programs, including Medicare, Medicaid, Medigap, VA, DOD, or TriCare, are not eligible for this program.

References:

1. NUEDEXTA [package insert]. Aliso Viejo, CA: Avanir Pharmaceuticals, Inc. **2.** Managed Markets Insight & Technology, LLC. October 27, 2021.

NUEDEXTA®
(dextromethorphan HBr and quinidine sulfate) capsules 20 mg / 10 mg

AVANIR PHARMACEUTICALS