Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: Nuedexta™

Common Name: dextromethorphan HBr and quinidine sulfate

PDL Category: Neurologics- Misc.

Comparable Products	Preferred Drug List Status
N/A	

Summary

Indications and Usage: Treatment of pseudobulbar affect (PBA). [1]

Mechanism of Action: Exact mechanism of action unknown. Dextromethorphan acts on sigma-1 and NMDA receptors in the brain. Quinidine is a metabolic inhibitor which allows for therapeutic concentrations of dextromethorphan.[1]

Dosage Forms: Capsules; Dextromethorphan hydrobromide 20mg and quinidine sulfate 10mg [1]

Recommended Dosage: 1 capsule by mouth once daily for 7 days, then 1 capsule twice daily thereafter. [1]

Common Adverse Drug Reactions: Diarrhea, dizziness, cough, vomiting, asthenia, peripheral edema, urinary tract infection, influenza, increased gamma-glutamyltransferase, and flatulence. [1]

Contraindications: Concomitant use with quinidine, quinine, or mefloquine. Patients with a history of quinidine, quinine or mefloquine-induced thrombocytopenia, hepatitis, or other hypersensitivity reactions. Patients with known hypersensitivity to dextromethorphan. Use with an MAOI or within 14 days of stopping an MAOI. Allow 14 days after stopping NUEDEXTA before starting an MAOI. Prolonged QT interval, congenital long QT syndrome, history suggestive of torsades de pointes, or heart failure. Complete atrioventricular (AV) block without implanted pacemaker, or patients at high risk of complete AV block. Concomitant use with drugs that both prolong QT interval and are metabolized by CYP2D6.[1]

Manufacturer: Avanir Pharmaceuticals Inc.

Analysis: Nuedexta™ is a combination product indicated for the treatment of PBA. In the trials used to gain FDA approval, Nuedexta™ was compared to placebo in patients with amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS). The primary outcome measure, laughing and crying episodes, was statistically significantly lower in the Nuedexta™ arm compared to placebo. The secondary endpoint was the Center for Neurologic Studies Lability Scale (CNS-LS) a seven-item self-report questionnaire with 3 items assessing crying and 4 assessing laughter. CNS-LS was also statistically significantly lower in the Nuedexta™ arm compared to placebo. Nuedexta™ has not been shown to be safe and effective in other types of emotional lability that can commonly occur, for example, in Alzheimer's disease and other dementias. Nuedexta™ carries the risk for many drug interactions and side effects. It is recommended that Nuedexta™ be added to the Preferred Drug List as a non-preferred drug for diagnosis confirmation.

IME Recommendation:

- ☐ Preferred Drug
- ☐ Recommended Drug
- ☒ Non-Preferred Drug
- ☐ Non-Recommended Drug
- ☐ Non-Preferred Drug with Conditions
- ☐ Refer to DUR for PA criteria

1. Nuedexta™ [package insert]. Aliso Viejo, CA: Avanir Pharmaceuticals Inc.; 2010.