Pharmacy Policy Bulletin

Title: Dextromethorphan hydrobromide and Quinidine sulfate (Nuedexta)

Policy #: Rx.01.24

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **dextromethorphan hydrobromide and Quinidine sulfate (Nuedexta®)** as provided under the member's prescription drug benefit.

Description:

Pseudobulbar affect (PBA) is a disinhibition syndrome characterized by uncontrolled laughing or crying disproportionate or inappropriate to the social context. The pathophysiology of PBA is not completely understood, but is thought to involve disruption of serotonin and glutamate pathways. PBA is associated with a variety of neurological disorders including amyotrophic lateral sclerosis, extrapyramidal and cerebellar disorders, multiple sclerosis, traumatic brain injury, Alzheimer's dementia, stroke, and brain tumors. Estimates of the prevalence of PBA vary widely, from 5% to over 50% depending on the patient population studied.

The goal of treating PBA is to diminish the frequency and severity of episodes. Treatment options include antidepressants, specifically selective serotonin reuptake inhibitors, tricyclic antidepressants, and dextromethorphan hydrobromide and quinidine sulfate.

Dextromethorphan hydrobromide and quinidine sulfate (Nuedexta®) is the first medications indicated for the treatment of PBA. Dextromethorphan hydrobromide (DM) and quinidine sulfate (Nuedexta®) is a combination of existing products, dextromethorphan and quinidine. DM is a sigma-1 receptor agonist and an uncompetitive NMDA receptor antagonist. Quinidine increases plasma levels of dextromethorphan by competitively inhibiting cytochrome P450 2D6, which catalyzes a major biotransformation pathway for dextromethorphan. The mechanism by which dextromethorphan exerts therapeutic effects in patients with pseudobulbar affect is unknown.

Policy:

INITIAL CRITERIA: Dextromethorphan hydrobromide and quinidine sulfate (Nuedexta®) is approved when both of the following are met:

1. Diagnosis of pseudobulbar affect; and
2. Prescribed by or in consultation with a neurologist or psychiatrist

Initial authorization: 6 months

REAUTHORIZATION CRITERIA: Dextromethorphan hydrobromide and quinidine sulfate (Nuedexta®) is re-approved when both of the following are met:

1. Documentation of clinical benefit from ongoing therapy (e.g. decrease in laughing/crying episodes); and
2. Prescribed by or in consultation with a neurologist or psychiatrist

Reauthorization: 2 years

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Ahmed A, Simmons Z. Pseudobulbar affect: prevalence and management. Therapeutics and Clinical Risk Management. 2013;9:483-9. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3849173/pdf/tcrm-9-483.pdf. Accessed March 30, 2021.

Nuedexta [package insert]. Aliso Viejo CA. Avanir Pharmaceuticals, Inc. January 2019. Available at: https://www.nuedexta.com/sites/default/files/Prescribing_Information.pdf. Accessed March 30, 2021.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Nuedexta®	Dextromethorphan hydrobromide and quinidine sulfate

Cross References:

Off-Label Use Rx.01.33

Policy Version Number:	12.00
P&T Approval Date:	March 18, 2021
Policy Effective Date:	July 01, 2021
Next Required Review Date:	March 18, 2022