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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	April 22, 2016
Subject:	Nuedexta	**Page:**	1 of 5

Last Review Date: September 6, 2024

Nuedexta

Description

Nuedexta (dextromethorphan hydrobromide/quinidine sulfate)

Background
Nuedexta is a combination product containing dextromethorphan hydrobromide and quinidine sulfate to treat pseudobulbar affect (PBA). PBA is a neurologic condition that can occur when certain neurologic diseases or brain injuries damage the areas of the brain that control normal expression of emotion. Emotional brain signaling is disrupted and triggers episodes of crying or laughing that are often sudden and exaggerated or do not match what the person is feeling inside. Conditions or injuries that can lead to PBA include Alzheimer's disease or other dementias, stroke, traumatic brain injury (TBI), multiple sclerosis (MS), Parkinson's disease, and Lou Gehrig's disease (ALS) (1).

Regulatory Status
FDA-approved indication: Nuedexta is a combination product containing dextromethorphan hydrobromide (an uncompetitive NMDA receptor antagonist and sigma-1 agonist) and quinidine sulfate (a CYP450 2D6 inhibitor) indicated for the treatment of pseudobulbar affect (PBA) (1).

Nuedexta contains quinidine and is contraindicated for concomitant use with other drugs containing quinidine, quinine, or mefloquine. Nuedexta is contraindicated in patients taking monoamine oxidase inhibitors (MAOIs) or in patients who have taken MAOIs in the past 14 days. It is also contraindicated in patients with a prolonged QT interval, congenital long QT syndrome or a history suggestive of torsades de pointes, and in patients with heart failure. Nuedexta is contraindicated in patients receiving drugs that both prolong QT interval and are metabolized by CYP2D6. Nuedexta is contraindicated in patients with complete atrioventricular

(AV) block without implanted pacemakers, or in patients who are at high risk of complete AV block (1).

Nuedexta should not be taken more than twice per day. The total dose should not exceed 40 mg/20 mg daily. The need for continued treatment should be reassessed periodically, as spontaneous improvement of PBA occurs in some patients (1).

Safety and effectiveness in pediatric patients have not been established (1).

Related Policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Nuedexta may be considered **medically necessary** if the conditions indicated below are met.

Nuedexta may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Pseudobulbar affect (PBA)

AND ONE of the following:

1. Alzheimer's disease or other dementias
2. Stroke
3. Traumatic brain injury (TBI)
4. Multiple Sclerosis (MS)
5. Parkinson's disease
6. Lou Gehrig's disease (ALS)

AND ALL of the following:

1. Inadequate treatment response, intolerance, or contraindication to treatment with:
    a. Selective serotonin reuptake inhibitor (SSRI)
    b. Tricyclic antidepressant (TCA)
2. Prescriber agrees to evaluate for a spontaneous improvement of PBA prior to request for renewal
3. Baseline ECG with no significant abnormalities and **NO** history of QT prolongation syndrome
4. **NO** history of complete AV (atrioventricular) block without an implanted pacemaker, or be at high risk of complete AV block
5. **NO** history of torsades de pointes, or heart failure
6. Patients must have a baseline score of at least 13 on the Center for Neurologic Studies-Lability Scale (CNS-LS)
   (e.g., https://www.nuedextahcp.com/sites/default/files/pdf/CNS-LS-Questionnaire.pdf)

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Pseudobulbar affect (PBA)

AND ALL of the following:

1. Consultation with a neurologist to ascertain positive clinical response to therapy
2. Patient has been assessed for spontaneous improvement and symptoms have returned
3. Prescriber agrees to evaluate for a spontaneous improvement of PBA prior to request for renewal
4. Prescriber agrees to reevaluate ECG if risk factors for arrhythmia change during the course of treatment
5. Patient's CNS-LS score has stabilized or decreased from baseline
   (e.g., https://www.nuedextahcp.com/sites/default/files/pdf/CNS-LS-Questionnaire.pdf)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 180 capsules per 90 days

Duration 3 months

Prior – Approval *Renewal* Limits

Quantity 180 capsules per 90 days

Duration 6 months

Rationale

Summary

Nuedexta is a combination product containing dextromethorphan hydrobromide and quinidine sulfate to treat PBA. Nuedexta should be taken no more than twice per day. The total dose should not exceed 40 mg/20 mg daily. The need for continued treatment should be reassessed periodically, as spontaneous improvement of PBA occurs in some patients. Nuedexta is contraindicated in those with a prolonged QT interval, heart failure, and in patients who have taken MAOIs within the preceding 14 days. Safety and effectiveness in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Nuedexta while maintaining optimal therapeutic outcomes.

References

1. Nuedexta [package insert]. Rockville, MD: Otsuka America Pharmaceuticals, Inc.; December 2022.

Policy History

Date	Action
April 2016	Addition to PA
September 2016	Annual editorial review and reference update

April 2017	Removal of requirement to discontinue therapy for two weeks
June 2017	Annual review
November 2017	Addition of baseline ECG with no significant abnormalities and **NO** history of QT prolongation syndrome and no history of complete AV (atrioventricular) block without an implanted pacemaker or be at high risk of complete AV block. NO history of torsades de pointes, or heart failure Addition of baseline score of at least 13 on the Center for Neurologic Studies-Lability Scale (CNS-LS) Addition of consultation with a neurologist to ascertain improvement in the renewal section
March 2018	Annual review
December 2019	Annual review and reference update
December 2020	Annual review
March 2021	Revised the following renewal requirements per FEP: Changed from "Consultation with a neurologist to ascertain improvement" to "Consultation with a neurologist to ascertain positive clinical response to therapy". Changed from "Patients must have decrease in score on the CNS-LS" to "Patient's CNS-LS score has stabilized or decreased from baseline". Added updated link for CNS-LS scoring tool
June 2021	Annual review
September 2022	Annual review
March 2023	Annual review
September 2023	Annual review and reference update
September 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.