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 in patients 18 years of age or older for the treatment of pseudobulbar affect (PBA) and if the conditions indicated below are met.

Nuedexta is considered investigational in patients less than 18 years of age and 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) (available at http://www.cmeinstitute.com/Psychlopedia/Documents/specialtopic/13eai/sec1/AV6.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 improvement
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. Patients must have decrease in score on the CNS-LS
**Policy Guidelines**

**Pre - PA Allowance**
None

**Prior - Approval Limits**

<table>
<thead>
<tr>
<th>Quantity</th>
<th>180 capsules per 90 days</th>
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<tbody>
<tr>
<td>Duration</td>
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**Prior – Approval Renewal Limits**

<table>
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<th>Quantity</th>
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<td>Duration</td>
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**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, hear 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**

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>April 2016</td>
<td>Addition to PA</td>
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<tr>
<td>September 2016</td>
<td>Annual editorial review and reference update</td>
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Section: Prescription Drugs  Effective Date: January 1, 2020
Subsection: Central Nervous System Drugs  Original Policy Date: April 22, 2016
Subject: Nuedexta  Page: 5 of 5

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

Keywords

*This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.*