BlueCross BlueShield
Federal Employee Program.

NUEDEXTA

(dextromethrorphan hydrobromide / quinidine sulfate)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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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.