Pharmacy Medical Necessity Guidelines: Nuedexta (dextromethorphan/quinidine)

Effective: May 12, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Nuedexta (dextromethorphan/quinidine) is a combination uncompetitive NMDA receptor antagonist/sigma-1 agonist and cytochrome P450 2D6 inhibitor Food and Drug Administration (FDA)-approved for the treatment of pseudobulbar affect (PBA). PBA occurs secondary to a variety of otherwise unrelated neurological conditions, and is characterized by involuntary, sudden, and frequent episodes of laughing and/or crying. PBA episodes typically occur out of proportion or incongruent to the patient's underlying emotional state.

FDA-APPROVED INDICATIONS

Nuedexta (dextromethorphan/quinidine) is indicated for the treatment of PBA.

COVERAGE GUIDELINES

The plan may authorize coverage of Nuedexta (dextromethorphan/quinidine) for Members, when the following criterion is met:

1. Documented diagnosis of pseudobulbar affect

AND

2. Member had an inadequate response, intolerance, or contraindication to at least two generic agents from either the tricyclic antidepressant (TCA) or selective serotonin reuptake inhibitor (SSRI) classes.

LIMITATIONS

None

CODES

None

REFERENCES

1. Colamonico J, Formella A, Bradley W. Pseudobulbar Affect: burden of illness in the U.S.A. Adv Ther. 2012 Sep;29(9):775-98. doi: 10.1007/s12325-012-0043-7. Epub 2012 Aug 30.
2. No authors listed. Dextromethorphan/quinidine (Nuedexta) for pseudobulbar affect. *Med Lett Drugs Ther*. 2011 Jul 11;53(1366):46-7.
3. Nuedexta (dextromethorphan/quinidine) [package insert]. Aliso Viejo, CA: Avanir Pharmaceuticals, Inc; June 2019.

APPROVAL HISTORY

May 10, 2011: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. April 10, 2012: No change
2. March 12, 2013: No changes
3. March 11, 2014: No changes
4. March 10, 2015: Remove the criteria of a diagnosis secondary to amyotrophic lateral sclerosis (ALS), multiple sclerosis (MS), or Bilateral Stroke.
5. January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
6. March 8, 2016: No changes.
7. February 14, 2017: No changes. Effective 02/14/17, Medical Necessity Guideline applies to Tufts Health Together.
8. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Added requirement for step therapy with one generic TCA and one generic SSRI.
9. June 12, 2018: No changes.
10. June 11, 2019: Updated the criteria to require previous trial of at least two generic antidepressants from either the TCA or SSRI classes. Administrative changes made to template.
11. May 12, 2020: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.