Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Nuedexta (dextromethorphan/quinidine)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***January 2011 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Nuedexta (dextromethorphan/quinidine).

Nuedexta (dextromethorphan/quinidine) is a combination products 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). Studies to support the effectiveness of dextromethorphan/quinidine (Nuedexta) were performed in patients with underlying amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS). Dextromethorphan/quinidine (Nuedexta) has not been shown to be effective in other types of emotional lability that can commonly occur, for example, in Alzheimer's disease or other dementias.

DEFINITIONS

NMDA – N-methyl- D-aspartate

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 underlying emotional state.

QT interval – a measure of the time between the start of the Q wave and the end of the T wave in the heart's electrical cycle. A prolonged QT interval is a risk factor for ventricular tachyarrhythmia and sudden death.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Nuedexta (dextromethorphan/quinidine), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by or in consultation with a neurologist
- Must have a diagnosis of pseudobulbar affect (PBA). Must supply chart documentation for the following to support the diagnosis of PBA:
    - Documentation that patient is experiencing involuntary outbursts of laughing and/or crying that are incongruous or disproportionate to the patient's emotional state
    - Documentation of a clinical work-up, including clinical rationale for the PBA diagnosis and exclusion of other possible conditions that could result in emotional lability (e.g. depression, bipolar disorder, schizophrenia, epilepsy)
- Must have an underlying neurological disorder such as amyotrophic lateral sclerosis (ALS), multiple sclerosis (MS), Alzheimer's and related diseases, Stroke, Traumatic Brain Injury (TBI), or Parkinsonian Syndromes.
- Must not be on concomitant therapy with any of the following medications:
    - Quinidine, quinine, or mefloquine

  - Monoamine oxidase inhibitors (MAOIs) within the past 14 days
  - Drugs that both prolong the QT interval and are metabolized by CYP2D6, such as thioridazine and pimozide
- Must not have a history of hypersensitivity to quinidine, quinine, mefloquine, or dextromethorphan
- Must not have a prolonged QT interval, congenital long QT syndrome or a history suggestive of torsades de pointes, heart failure, complete AV (atrioventricular) block without an implanted pacemaker, or be at high risk of complete AV block

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the provider showing a decrease in the number of laughing and/or crying episodes with Nuedexta therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Up to 1 year

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Nuedexta [package insert]. Aliso Viejo, CA: Avanir Pharmaceuticals. October 2010.
2. Pioro EP, Brooks BR, Cummings J, et al. Dextromethorphan plus ultra low-dose quinidine reduces pseudobulbar affect. *Ann Neurol.* 2010;68:693-702.
3. Panitch HS, Thisted RA, Smith RA, et al. Randomized, controlled trial of dextromethorphan/quinidine for pseudobulbar affect in multiple sclerosis. *Ann Neurol* 2006;59:780-787
4. Brooks BE, Thisted RA, Appel SH, et al. Treatment of pseudobulbar affect in ALS with dextromethorphan/quinidine, a randomized trial. *Neurology* 2004;63:1364-1370
5. Moore SR, Gresham LS, Bromberg MB et al. A self report measure of affective lability. *J Neurol Neurosurg Psychiatry* 1999;63:89-93
6. Robinson RG, Parikh RM, Lipsey JR. Pathological laughing and crying following stroke: validation of a measurement scale and a double-blind treatment study. *Am J Psychiatry* 1993;150:286-293
7. Arciniegas DB, Lauterbach EC, Ginsberg DL, et al. The differential diagnosis of pseudobulbar affect (PBA) among disorders of mood and affect. *CNS Spectr* 2005;10 (5 suppl):1-16

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*