SmartPA Criteria Proposal

Drug/Drug Class:	Nuedexta Clinical Edit
First Implementation Date:	February 18, 2021
Proposed Date:	October 17, 2023
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Nuedexta® (dextromethorphan hydrobromide and quinidine sulfate)

Why Issue Selected: Nuedexta®, a combination product of dextromethorphan hydrobromide and quinidine sulfate, is the first FDA approved treatment for pseudobulbar affect (PBA). PBA is a condition that typically presents in patients with neurological conditions or injuries that affect the way the brain controls emotion. The condition is characterized by episodes of sudden, uncontrollable, and inappropriate episodes of crying or laughing. PBA has a prevalence of approximately 2 million people in the United States with underlying conditions such as stroke, Alzheimer's disease, Parkinson's disease, multiple sclerosis, Lou Gehrig's disease (ALS), or traumatic brain injury. PBA shares several clinical features of mood disorders, however there are characteristic clinical features and validated scales to assist in determining an appropriate diagnosis and therapy. The Center for Neurologic Study – Lability Scale (CNS-LS) is a self-administered questionnaire that asks about the control of laughter and crying; this scale has been validated in patients with ALS and multiple sclerosis. The Pathological Laughter and Crying Scale (PLACS) is an interviewer administered scale assessing sudden episodes of laughter and crying; this scale has been validated in patients with acute stroke. MO HealthNet will impose clinical criteria to ensure appropriate utilization of Nuedexta therapy.

Program-Specific Information:

Date Range FFS 7-1-2022 to 6-30-2023			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
NUEDEXTA 20-10 MG CAPSULE	594	$659,612.19	$ 1,110.46

Type of Criteria:
- ☐ **Increased risk of ADE**
- ☒ **Appropriate Indications**
- ☐ **Preferred Drug List**
- ☒ **Clinical Edit**

Data Sources:
- ☐ **Only Administrative Databases**
- ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Nuedexta® (dextromethorphan hydrobromide and quinidine sulfate)
- Age range: All appropriate MO HealthNet participants aged 18 years or older

Approval Criteria

Initial Therapy:

- Participant aged 18 years or older **AND**
- Documented diagnosis of pseudobulbar affect **AND**
- Documentation of baseline episode frequency **AND**
- Participant has a Center for Neurologic Study-Lability Scale (CNS-LS) score of ≥ 13 **OR**
- Participant has a Pathological Laughter and Crying Scale (PLACS) score of ≥ 13

Continuation of therapy:

- Initial approval is for 6 months, renewal of prior authorization may be given for up to 12 months following documentation of the following:
  - Documentation of decrease in CNS-LS score or PLACS score from baseline **AND**
  - Documentation of decrease in episode frequency from baseline

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Claim exceeds 2 capsules per day
- Documented history of MAOI therapy in the past 45 days
- Documented history of quinidine, quinine, or mefloquine therapy in the past 45 days

Required Documentation

Laboratory Results:		Progress Notes:	**X**
MedWatch Form:		Other:	**X**

Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)
Rule Type: CE

Default Approval Period

1 year

References

- NUEDEXTA (dextromethorphan hydrobromide and quinidine sulfate) [package insert]. Aliso Viejo, CA: Avanir Pharmaceuticals, Inc.; December 2022.
- Ahmed A, Simmons Z. Pseudobulbar affect: prevalence and management. Ther Clin Risk Manag. 2013;9:483-489. doi:10.2147/TCRM.S53906
- Genetic and Rare Diseases Information Center. Pseudobulbar affect. Pseudobulbar affect | Genetic and Rare Diseases Information Center (GARD) – an NCATS Program (nih.gov). Accessed September 7, 2023.
- Avanir Pharmaceuticals, Inc. The Impact of PBA on Your Patients is Substantial. Impact of PBA on Patients | NUEDEXTA® (dextromethorphan HBr and quinidine sulfate) (nuedextahcp.com). Accessed September 7, 2023.