I. Requirements for Prior Authorization of Nuedexta

A. Prescriptions That Require Prior Authorization

All prescriptions for Nuedexta must be prior authorized.

B. Clinical Review Guidelines and Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Nuedexta, the determination of whether the requested prescription is medically necessary will take into account whether the recipient:

1. Is 18 years of age or older

AND

2. Has a diagnosis of pseudobulbar affect (PBA)

AND

3. Has been prescribed Nuedexta by or in consultation with a neurologist

AND

4. Is not receiving concomitant therapy with quinidine, quinine, or mefloquine

AND

5. Does not have a history of quinidine, quinine, or mefloquine-induced thrombocytopenia, hepatitis, or other hypersensitivity reactions

AND

6. Does not have a known hypersensitivity to dextromethorphan

AND

7. Is not receiving concomitant therapy with a monoamine oxidase inhibitor (MAOI) and is not within 14 days of receiving a dose of an MAOI

AND

8. Has a recent EKG that does not show a prolonged QT interval or AV block without implanted pacemaker

AND

9. Does not have a known history of heart failure, history suggestive of torsades de pointes, and is not at high risk for complete AV block.

AND

10. Is not receiving concomitant therapy with medications that prolong the QT interval and are metabolized by CYP2D6.

AND

11. Has had all drug interactions addressed that may occur between Nuedexta and the recipient's current medications (such as but not limited to SSRI's, tricyclic antidepressants, CYP2D6 substrates, CYP3A4 inhibitors, medications that prolong the QT interval, and digoxin)

AND

12. For patients at risk of QT prolongation and torsades de pointes, whether the recipient has had a baseline EKG and will receive an EKG evaluation 3-4 hours after the first dose. Patients at high risk of QT prolongation and torsades de pointes include recipients concomitantly taking any CYP3A4 inhibitors or medication which may prolong the QT interval and recipients with left ventricular hypertrophy or left ventricular dysfunction.

AND

13. Has potassium and magnesium levels within normal range

AND

14. Does not have severe renal impairment defined as a GFR less than 30.

OR

15. Does not meet the clinical review guidelines listed above but in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

FOR RENEWALS OF PRESCRIPTIONS FOR NUEDEXTA: Requests for prior authorization of renewals of prescriptions for Nuedexta that were previously approved will take into account whether the recipient:

1. Is not receiving concomitant therapy with quinidine, quinine, or mefloquine

AND

2. Is not receiving concomitant therapy with a monoamine oxidase inhibitor (MAOI) and is not within 14 days of receiving a dose of an MAOI

AND

3. Is not receiving concomitant therapy with medications that prolong the QT interval and are metabolized by CYP2D6

AND

4. Had all drug interactions addressed that may occur between Nuedexta and the recipient's current medications (such as but not limited to SSRI's, tricyclic antidepressants, CYP2D6 substrates, CYP3A4 inhibitors, medications that prolong the QT interval, and digoxin)

AND

5. Had the recommended monitoring to ensure the safety of continued use of Nuedexta including all of the following:
    a. Repeat EKG if risk factors for arrhythmia change during the course of treatment with Nuedexta. (Risk factors include concomitant use of drugs associated with QT prolongation, electrolyte abnormalities (potassium and magnesium), bradycardia, and family history of QT abnormality.)
    b. Potassium and magnesium levels
    c. Complete blood count (CBC)
    d. Liver Function Tests (LFT)
    e. GFR

AND

6. Has documented improvement in PBA symptoms

OR

7. Does not meet the clinical review guidelines listed above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of the request for a prescription for Nuedexta. If the guidelines in Section B are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

D. Dose and Duration of Therapy

The Department will:

- Limit initial approval of Nuedexta to 2 months of therapy.
- Approve renewal of Nuedexta for up to 12 months of therapy

E. References:

1. Nuedexta Package Insert, Avanir Pharmaceuticals, Inc. January , 2015

2. Symptom-based management of amyotrophic lateral sclerosis UpToDate ONLINE. Updated February 18, 2011. Accessed April 25th, 2011.