

SPECIALTY GUIDELINE MANAGEMENT

BRINEURA (cerliponase alfa)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Brineura is indicated to slow the loss of ambulation in symptomatic pediatric patients 3 years of age and older with late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency.

All other indications are considered experimental/investigational and are not a covered benefit.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review: tripeptidyl peptidase 1 (TPP1) enzyme assay or genetic testing results supporting diagnosis.

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a neurologist.

IV. CRITERIA FOR APPROVAL

Late infantile neuronal ceroid lipofuscinosis type 2 (CLN2)

Authorization of 12 months may be granted for members with CLN2 when ALL of the following criteria are met:

1. Diagnosis of CLN2 was confirmed by enzyme assay demonstrating a deficiency of tripeptidyl peptidase 1 (TPP1) enzyme activity or by genetic testing.
2. Brineura is prescribed to slow the loss of ambulation in symptomatic members
3. Member is 3 years of age or older
4. Brineura will be administered by, or under the direction of a physician knowledgeable in intraventricular administration

V. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

VI. REFERENCES

1. Brineura [package insert]. Novato, CA: BioMarin Pharmaceutical, Inc. April 2017.
2. Fietz M, AISayed M, Burke, D, et al. Diagnosis of neuronal ceroid lipofuscinosis type 2 (CLN2 disease): Expert recommendations for early detection and laboratory diagnosis. *Molecular Genetics and Metabolism*. 2016 (11): 160-167.