Overview
Brineura (cerliponase alfa) is a hydrolytic lysosomal N-terminal tripeptidyl peptidase 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.

Coverage Guidelines
Authorization may be granted for members who are currently receiving treatment with Brineura, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR
Authorization may be granted for Brineura when all the following criteria are met, and clinical documentation has been submitted:

1. Documented diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), confirmed by TPP1 deficiency or genetic testing
2. The prescribing provider is a neurologist
3. The member is at least 3 years of age

Continuation of Therapy
Reauthorizations may be approved when documentation is submitted that initial criteria have been met.

Limitations
Initial approvals and reauthorizations will be for 6 months.

References

399 Revolution Drive, Suite 810, Somerville, MA 02145 | allwayshealthpartners.org

AllWays Health Partners includes AllWays Health Partners, Inc. and AllWays Health Partners Insurance Company

Review History
04/17/2019 – Reviewed
05/20/2020 – Reviewed and Updated May P&T Mtg; added started and stabilized statement; updated ‘Overview’; references updated. Effective 8/1/20.

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