

Policy Name:	Brineura (cerliponase alfa)	Policy #:	2606P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Brineura.

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Brineura under the Specialty Medical benefit when the following criteria have been met.

Criteria

1. Coverage Criteria

- 1.1 Diagnosis of Neuronal Ceroid Lipofuscinosis Type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency and Jansky-Bielschowsky disease confirmed by TPP1 deficiency or the detection of pathogenic mutations in each allele of the TPP1 gene (also known as the CLN2 gene)
- 1.2 Ordered by a Neurologist (central nervous system doctor) or provider specializing in the treatment of Neuronal Ceroids Lipofuscinosis Type 2
- 1.3 Documentation member is currently ambulatory (able to move independently with minimal mobility aids)

2. Exclusion Criteria

- 2.1 Acute intraventricular access device-related complications (e.g., leakage, device failure, or device-related infection) or a ventriculoperitoneal shunt (shunt in the brain that drains excess cerebrospinal fluid (CSF))

3. Approval Period

- 3.1 Initial Approval: 12 months
- 3.2 Subsequent Approvals: 12 months, with documentation indicating that the use of Brineura has slowed the loss of ambulation from baseline

CPT Codes

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HCPCS Codes

J0567	Injection, cerliponase alfa, 1 mg
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References

1. Brineura (cerliponase alfa) [prescribing information]. Novato, CA:BioMarin Pharmaceutical Inc; March 2020.
2. Mole SE, Schulz A, Badoe E, et al. Guidelines on the diagnosis, clinical assessments, treatment and management for CLN2 disease patients. Orphanet J Rare Dis 2021; 16:185.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.