# Pharmacy Drug Policy & Procedure

| 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 Age 3 years or older

1.3 Ordered by a Neurologist (central nervous system doctor) or provider specializing in the treatment of Neuronal Ceroids Lipofuscinosis Type 2

1.4 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

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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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