

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

## Brineura (cerliponase alfa)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Brineura (cerliponase alfa)

### APPROVAL CRITERIA

Requests for Brineura (cerliponase alfa) may be approved for:

- I. Symptomatic individuals with a diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) as confirmed by:
  - A. Tripeptidyl peptidase 1 (TPP1) deficiency;
  - OR**
  - B. Detection of pathogenic mutations in each allele of the TPP1 gene (also known as the neuronal ceroid lipofuscinosis type 2 gene);
- AND**
- II. Treatment is being given to slow the loss of ambulation.

Brineura (cerliponase alfa) may not be approved for the following:

- I. There are acute intraventricular access device-related complications (such as, leakage, device failure, or device-related infection) or ventriculoperitoneal shunts; **OR**
- II. Individual has signs or symptoms of acute or unresolved localized infection on or around the device insertion site (such as, cellulitis or abscess), **OR**
- III. Individual has suspected or confirmed central nervous system (CNS) infection (such as, cloudy cerebrospinal fluid [CSF], or positive CSF gram stain, or meningitis).

Requests for Brineura (cerliponase alfa) may not be approved when the above criteria are not met and for all other indications.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply. CRX-ALL-0474-19

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**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: August 26, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. Online Mendelian Inheritance in Man (OMIM) #204500 Ceroid Lipofuscinosis, Neuronal, 2; CLN2. Available from: <https://www.omim.org/entry/204500>. Accessed on: August 26, 2019.

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