

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

*FHK- Florida Healthy Kids

Brineura (cerliponase alfa)

DRUG.00099

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Brineura (cerliponase alfa)

APPROVAL CRITERIA

Requests for Brineura (cerliponase alfa) may be approved when the following criteria are met:

- I. Individual has late infantile neuronal ceroid lipofuscinosis type 2; **AND**
- II. Individual is symptomatic and the diagnosis of ceroid lipofuscinosis type 2 was confirmed by TPP1 deficiency or the detection of pathogenic mutations in each allele of the TPP1 gene (also known as the neuronal ceroid lipofuscinosis type 2 gene); **AND**
- III. Treatment is being given to slow the loss of ambulation; **AND**
- IV. There is no documentation of acute intraventricular access device-related complications (for example, leakage, device failure, or device-related infection) or ventriculoperitoneal shunts.

Requests for Brineura (cerliponase alfa) may **not** be approved for all other indications.

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

Key References:

BioMarin Pharmaceutical. A multicenter, multinational, extension study to evaluate the long-term efficacy and safety of BMN 190 in patients with CLN2 disease. NLM Identifier: NCT02485899. Last updated on November 1, 2016. Available at: <https://clinicaltrials.gov/ct2/show/NCT02485899?term=cerliponase+alfa&rank=2>. Accessed on October 23, 2017.

BioMarin Pharmaceutical. A phase 1/2 open-label dose-escalation study to evaluate safety, tolerability, pharmacokinetics, and efficacy of intracerebroventricular BMN 190 in patients with late-infantile neuronal ceroid lipofuscinosis (CLN2) disease. NLM Identifier: NCT01907087. Last updated on April 27, 2016. Available at: <https://clinicaltrials.gov/ct2/show/NCT01907087?term=cerliponase+alfa&rank=1>. Accessed on December 22, 2017.

Brineura™ [Product Information], San Rafael, CA. Biomarin, April 2017. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761052lbl.pdf. Accessed on October 23, 2017.

Cerliponase alfa. In: DrugPoints System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated April 27, 2017. Available at: <http://www.micromedexsolutions.com>. Accessed on October 23, 2017.

PAGE 1 of 1 03/09/2018
New Program Date 05/15/2017

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.

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