PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Brineura (cerliponase alfa)
BILLING CODE	J3590 (1 unit = 1 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient Hospital/Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 600 mg every 28 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Brineura (cerliponase alfa) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

INFANTILE NEURONAL CEROID LIPOFUSCINOSIS TYPE 2 (CLN2), aka tripeptidyl peptidase 1 (TPP1) deficiency

For **initial** authorization:

1. Medication is being used 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; AND
2. Member is between the ages 3 and 16 years old; AND
3. Member has mild to moderate disease documented by a two-domain score of 3-6 on motor and language domains of the Hamburg Scale, with a score of at least 1 in each of these two domains; AND
4. Member does not have a score of 0 points on the combined motor and language components of the Hamburg CLN2 rating scale; AND
5. Member does not have another neurological illness that may have caused cognitive decline (e.g. trauma, meningitis, or hemorrhage); AND
6. Member does not require ventilation support; AND
7. Member does not have generalized motor status epilepticus within 4 weeks of first dose.
8. **Dosage allowed:** 300 mg administered once every other week as an intraventricular infusion followed by infusion of Intraventricular Electrolytes over approximately 4.5 hours.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Member's loss of ambulation slowed and it is documented in chart notes.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Brineura (cerliponase alfa) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
05/17/2017	New policy for Brineura created.

References:

1. ClinicalTrials.gov. BMN 190. Available at: https://clinicaltrials.gov/ct2/results?term=bmn+190&Search=Search. Accessed January 1, 2017.
2. ClinicalTrials.gov. A phase 2 open-label study to evaluate safety, tolerability, and efficacy of intracerebroventricular BMN 190 in patients with CLN2 disease. Available at: https://clinicaltrials.gov/ct2/show/NCT02485899?term=bmn+190&rank=3. Accessed January 8, 2017.
3. Brineura [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; April, 2017.
4. FDA.gov. FDA approves first treatment for a form of Batten disease. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm555613.htm. Accessed May 17, 2017.

Effective date: 07/01/2017
Revised date: 05/17/2017