Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 27, 2023

BRINEURA® (cerliponase alfa)

LENGTH OF AUTHORIZATION: 1 year

REVIEW CRITERIA:

- Patient must be ≥ 3 years of age.
- Patient must have a documented diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) (also known as tripeptidyl peptidase 1 [TPP1] deficiency) confirmed by at least one of the following:
    - Official labs demonstrating deficient TPP1 enzyme activity (in leukocytes, fibroblasts, or dried blood spots); **OR**
    - Genetic testing results identifying causative mutations of the TPP1/CLN2 gene.
- Baseline score for the Motor domain of a CLN2 Clinical Rating Scale (the results including the assessment tool must be provided.
    - Motor domain CLN2 Clinical Rating Scale scores:
        - Walks normally (score = 3)
        - Frequent falls, clumsiness evident (score = 2)
        - No unaided walking or only crawling (score = 1)
        - Immobile, mostly bedridden (score = 0)
- Must be prescribed by, or in consultation with a neurologist or physician that specializes in the treatment of neuronal ceroid lipofuscinosis (NCL) diseases.

CONTINUATION OF THERAPY:

- Documentation of improved clinical response with no signs of disease progression; **AND**
- Patient has not demonstrated a decline in the Motor domain of the CLN2 Clinical Rating Scale score (documentation of current results/score must be provided); **AND**
- Patient has not experienced any treatment-restricting adverse effects; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 150 mg/5 mL (30 mg/mL) solution, two single-dose vials per carton co-packaged with Intraventricular Electrolytes Injection 5 mL in a single-dose vial.