<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Brineura (cerliponase alfa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BILLING CODE</td>
<td>C9014 (1 unit = 1 mg)</td>
</tr>
<tr>
<td>BENEFIT TYPE</td>
<td>Medical</td>
</tr>
<tr>
<td>SITE OF SERVICE ALLOWED</td>
<td>Outpatient Hospital/Office</td>
</tr>
<tr>
<td>COVERAGE REQUIREMENTS</td>
<td>Prior Authorization Required (Non-Preferred Product)</td>
</tr>
<tr>
<td>QUANTITY LIMIT</td>
<td>600 mg every 28 days</td>
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**PHARMACY POLICY STATEMENT**

**Ohio Medicaid**

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 lipofuscinoses 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.
<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tbody>
<tr>
<td>05/17/2017</td>
<td>New policy for Brineura created.</td>
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</table>

References:

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