

Field Name	Field Description
Prior Authorization Group Description	<b>Brineura (cerliponase alfa)</b>
Drugs	Brineura (cerliponase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert, and/or per the National Comprehensive Cancer Network (NCCN)
Exclusion Criteria	N/A
Required Medical Information	See “other criteria”
Age Restrictions	Member must be 3 years of age or older
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	If the criteria are met, the request will be approved for 12 months.
Other Criteria	<p><b><u>Initial Authorization:</u></b></p> <ul style="list-style-type: none"> <li>• Documentation of confirmed diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) with one of the following: <ul style="list-style-type: none"> <li>○ Lab results demonstrating deficient TPP1 enzyme activity</li> <li>○ Identification of causative mutations in the TPP1/CLN2 gene</li> </ul> </li> <li>• Documentation of baseline CLN2 Clinical Rating Scale motor +language score. Baseline CLN2 score must be &gt; 0.</li> <li>• Medication is prescribed at an FDA approved dose</li> </ul> <p><b><u>Re-authorization:</u></b></p> <ul style="list-style-type: none"> <li>• Documentation of CLN2 Clinical Rating Scale motor +language score has remained &gt; 0</li> <li>• Medication is prescribed at an FDA approved dose</li> </ul>
Revision/Review Date: 7/2024	<b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</b>