

| 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 6 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>• Prescribed dose is consistent with FDA-approved labeling</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>• Prescribed dose is consistent with FDA-approved labeling</li> </ul> |
| Revision/Review Date: 7/2023          | <b>Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</b>   |

PerformRx recommends approving the Brineura prior authorization criteria with no changes for ACOH.