

<u>Field Name</u>	<u>Field Description</u>
<u>Prior Authorization Group Description</u>	<u>Brineura (cerliponase alfa)</u>
<u>Drugs</u>	<u>Brineura (cerliponase alfa)</u>
<u>Covered Uses</u>	<u>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)</u>
<u>Exclusion Criteria</u>	<u>N/A</u>
<u>Required Medical Information</u>	<u>See “other criteria”</u>
<u>Age Restrictions</u>	<u>Member must be 3 years of age or older</u>
<u>Prescriber Restrictions</u>	<u>Prescriber must be a neurologist</u>
<u>Coverage Duration</u>	<u>If the criteria are met, the request will be approved for 6 months.</u>
<u>Other Criteria</u>	<p><u>**Drug is being requested through the member’s medical benefit**</u></p> <p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • <u>Documentation of confirmed diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) with one of the following:</u> <ul style="list-style-type: none"> ○ <u>Lab results demonstrating deficient TPP1 enzyme activity</u> ○ <u>Identification of causative mutations in the TPP1/CLN2 gene</u> • <u>Prescribed dose is consistent with FDA-approved labeling</u> • <u>Documentation of baseline CLN2 Clinical Rating Scale motor +language score. Baseline CLN2 score must be > 0.</u> <p><u>Re-authorization:</u></p> <ul style="list-style-type: none"> • <u>Prescribed dose is consistent with FDA-approved labeling</u> • <u>Documentation of CLN2 Clinical Rating Scale motor +language score has remained > 0</u> <p><u>Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</u></p>
<u>Revision/Review Date: 6/2021</u>	