SENTARA COMMUNITY PLAN
(MEDICAID)

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-305-2331**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

Drug Requested: Brineura™ (cerliponase alfa) **(J3590, C9399) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

- ❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dosage: 300 mg once every other week given by intraventricular (ICV) infusion

- Quantity Limits: 300 billable units (1 kit containing 2 vials) every 14 days

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Approval – 6 months

- ❑ Member is at least 37 weeks post-menstrual age (gestational age at birth plus post-natal age) and weighs at least 2.5 kg

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- ❑ Member must not have any acute intraventricular access device-related complications (e.g., leakage, extravasation of fluid, or device failure)
- ❑ Member must not have ventriculoperitoneal shunts
- ❑ Member has no signs or symptoms of acute, unresolved localized infection on or around the device insertion site (e.g., cellulitis or abscess); or a suspected or confirmed CNS infection (e.g., cloudy CSF, positive CSF gram stain, or meningitis)
- ❑ Member must have a definitive diagnosis of late infantile CLN2 confirmed by deficiency of the lysosomal enzyme tripeptidyl peptidase-1 (TPP1) and/or molecular analysis indicating two (2) pathogenic variants/mutations in the TPP1/CLN2 gene on chromosome 11p15
- ❑ Member is ambulatory
- ❑ Members with a history of bradycardia, conduction disorder, or with structural heart disease will have electrocardiogram (ECG) monitoring performed during each infusion

Reauthorization: 6 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied. To qualify, documentation must be submitted.

- ❑ Member continues to meet the relevant criteria identified in the initial criteria
- ❑ Member has an absence of unacceptable toxicity from the drug or complications from the device
- ❑ Member has had a 12-lead ECG evaluation performed within the last 6 months
- ❑ Member is being continuously monitored for a beneficial response to therapy

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*

REVISED/UPDATED/REFORMATTED: ~~4/6/2018; 5/25/2018; 8/17/2018; 10/8/2018; 2/4/2019; 7/22/2019; 10/16/2019; 10/16/2020;~~ **65/8/2026**