ATRIO HEALTH PLANS

Brineura

Brineura (cerliponase alfa) J0567

Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ Documentation is provide that symptomatic Patients with a diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) is confirmed by:
- ☐ Tripeptidyl peptidase 1 (TPP1) deficiency, and documentation is provided; OR
- ☐ Detection of pathogenic mutations in each allele of the TPP1 gene (also known as the neuronal ceroid lipofuscinosis type 2 gene), and documentation is provided; AND

☐ Documentation is provided that Patient has all of the following on the CLN2 Clinical Rating Scale:
- ☐ Aggregate motor-language domain score of 3 or greater; AND
- ☐ Score of at least 1 on the motor domain; AND
- ☐ Score of at least 1 on the language domain; AND

☐ Treatment is being given to slow the loss of ambulation.

Continued >>>>

Brineura (cerliponase alfa) may NOT be approved for the following:

- There are acute intraventricular access device-related complications (such as leakage, device failure, or device-relatedinfection) or ventriculoperitoneal shunts; OR
- Patient has signs or symptoms of acute or unresolved localized infection on or around the device insertion site (such as, cellulitis or abscess), OR
- Patient has suspected or confirmed central nervous system (CNS) infection (such as, cloudy cerebrospinal fluid [CSF], or positive CSF gram stain, or meningitis);

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ Continuation requests for Brineura (cerliponase alfa) may be approved for:

- ☐ Documentation is provided that Patient has a score of at least 1 on the motor domain of the CLN2 Clinical Rating Scale;
- ☐ Treatment is being given to slow the loss of ambulation.

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Brineura Drug PA

Drug Name(s):
BRINEURA **CERLIPONASE ALFA**

Criteria for approval of Prior Authorization Drug:
1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:
N/A

Prescriber Restrictions:
Pediatric Neurologist or related specialist

Coverage Duration:
Approval length determined on individual basis.

FDA Indications:
Brineura

- Asthma (Severe), Add-on maintenance therapy

Off-Label Uses:
N/A

Age Restrictions:

- 3 years or older

Other Clinical Considerations:
Contraindications:

- Acute, unresolved localized infection on or around the device insertion site (eg, cellulitis or abscess); or suspected or confirmed CNS infection (cloudy cerebrospinal fluid (CSF) or positive CSF gram stain or meningitis)
- Any acute intraventricular access device complications (eg, leakage, extravasation of fluid, or device failure)
- Ventriculoperitoneal shunts

Resources:
https://www.micromedexsolutions.com/micromedex2/librarian/CS/2B4633/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/DCC9E0/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=932227&contentSetId=100&title=Cerliponase+Alfa&servicesTitle=Cerliponase+Alfa&brandName=Brineura&UserMdxSearchTerm=Brineura&=null#