

Medical prior authorization form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: **Commercial (Traditional)** **Commercial (Individual/Optimized)**

Medicaid

This request is: **Urgent** (life threatening) **Non-Urgent** (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

Brineura[®] (cerliponase alfa)

Member

Last Name: _____ First Name: _____

ID #: _____ DOB: _____ Gender: _____

Primary Care Physician: _____

Requesting Physician: _____ Phone: _____ Fax: _____

Physician Address: _____

Physician NPI: _____ Contact Name: _____

Physician Signature: _____ Date: _____

Product and Billing Information

New request Continuation of therapy

Drug product: Brineura 300 mg/10 mL kit Dose: _____

Dosing Frequency: _____

Date of last dose: _____

Date of next dose: _____

Administration: Physician's Office
 Outpatient Infusion
Facility: _____ NPI: _____ Fax #: _____

Home infusion
Agency: _____ NPI: _____ Fax #: _____

Billing: Physician Buy and Bill
 Facility Buy and Bill
 Specialty Pharmacy
Pharmacy: _____ NPI: _____ Fax #: _____

ICD-10 Diagnosis code(s): _____

Precertification Requirements

Before this drug is covered, the patient must meet all of the following requirements (initial approval limited to 6 months):

1. Must be ordered by a neurologist.
2. Must have a diagnosis of late-infantile neuronal ceroid lipofuscinosis type 2 (CLN2) disease which was confirmed by tripeptidyl peptidase 1 (TPP1) deficiency.
3. Patient must be symptomatic.
4. Patient must be 3 years of age or older.
5. Treatment is being given to slow the loss of ambulation in a patient with a baseline motor-language CLN2 clinical rating scale (CRS) greater than or equal to 3 (see table on next page).

For reauthorization the patient must meet all of the continuation criteria (reauthorization is required every 6 months):

1. Must meet all of the initial requirements.
2. Patient has a score of 1 or higher in the motor domain of the CLN2 clinical rating scale (see table on next page).
3. Clinical documentation, including chart notes, of disease stability or improvement must be provided.

Note: Authorization for indications not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the drug's use for the identified indication.

Priority Health Precertification Documentation

A. What condition is this drug being requested for?

- Late-infantile neuronal ceroid lipofuscinosis type 2 (CLN2) disease
- Other – rationale for use: _____

B. Please fax testing showing TPP1 deficiency.

C. Please fax chart notes detailing the patients symptoms and disease course.

D. What is the patient's baseline motor-language CLN2 CRS score (see table below)? _____

Recertification Documentation

A. What condition is this drug being requested for? _____

B. Please fax testing showing TPP1 deficiency.

C. What is the patient's motor domain of the CLN2 clinical rating scale? _____

D. Please fax documentation of disease stability or improvement since starting Brineura.

Additional information

CLN2 Clinical Rating Scale description

	Description	Score
Primary Analysis		
Motor	Walk normally	3
	Frequent falls, ataxia, independent walk > 10 steps	2
	No unaided gait	1
	Immobile, mostly bedridden	0
Language	Normal	3
	Loss of words, intelligible but abnormal speech	2
	Some comprehension, mostly unintelligible speech	1
	Unintelligible or no speech	0