OPTIMA HEALTH PLAN

PHARMACY/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 1-844-668-1550**. 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 will be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

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

DRUG INFORMATON: Authorization may be delayed if incomplete.

Drug Form/Strength/Quantity: _____

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

Diagnosis: _____ **ICD Code**: _____

RECOMMENDED DOSAGE: 300 mg once every other week given by intraventricular (ICV) infusion

- Following administration, member must also receive intraventricular electrolyte infusion

❑ 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.

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 - 12 months.

❑ Member must be 3 years of age or older,

AND

❑ Member must have a documented diagnosis of symptomatic late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency and Jansky-Bielschowski disease

AND

❑ Diagnosis of CLN2 must have been confirmed by TPP1 deficiency or the detection of pathogenic mutations in each allele of the TPP1 gene (also known as the CLN2 gene)

AND

❑ Member is symptomatic

AND

❑ Member does not have acute intraventricular access device-related complications (i.e. leakage, device failure, or device-related infection) or a ventriculoperitoneal shunt

(Continued on next page; signature page is required to process request.)

(Please ensure signature page is attached to form.)

Reauthorization/Continued Approval - 12 months. To qualify, documentation must be submitted.

- ❑ Member must demonstrate that ambulation loss has slowed from baseline

Medication being provided by (check box below that applies):

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

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Optima Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Optima'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.****

Member Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

***Approved by Pharmacy and Therapeutics Committee:** 11/16/2017
REVISED/UPDATED: ~~3/28/2018; 5/18/2018;~~ **(Reformatted)** ~~3/15/2019; 7/6/2019;~~ **9/16/2019**