pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
December 27, 2017	January 8, 2018	*See Below

SUBJECT

Prior Authorization of Brineura (cerliponase alfa) - Pharmacy Services

BY

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Office of Medical Assistance Programs

New IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994.

PURPOSE:

The purpose of this bulletin is to:

1. Inform providers that the Department of Human Services (DHS) will require prior authorization of prescriptions for Brineura (cerliponase alfa)
2. Issue handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Brineura (cerliponase alfa) for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance Program and providing services in the fee-for-service delivery system, including pharmacy services to residents of long-term care facilities.

BACKGROUND:

The DHS Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the DHS Prospective Drug Use Review and Retrospective Drug Use Review programs.

*01-17-41	09-17-40	27-17-38	
02-17-36	11-17-36	30-17-37	
03-17-36	14-17-37	31-17-42	
08-17-43	24-17-37	32-17-36	33-17-41

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll free number for your provider type

Visit the Office of Medical Assistance Programs Web site at
http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm

DISCUSSION:

During the September 20, 2017 DUR Board meeting, the DUR Board recommended that DHS require prior authorization of Brineura (cerliponase alfa) to ensure safe and appropriate utilization. The DUR Board recommended guidelines to determine medical necessity of Brineura (cerliponase alfa) which were subject to public review and comment, and subsequently approved for implementation by DHS.

PROCEDURE:

The procedures for prescribers to request prior authorization of Brineura (cerliponase alfa) are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. DHS will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Brineura (cerliponase alfa)) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

SECTION II
Brineura (cerliponase alfa)

Requirements for Prior Authorization of Brineura (cerliponase alfa)

A. Prescriptions That Require Prior Authorization

All prescriptions for Brineura (cerliponase alfa) require prior authorization.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of Brineura (cerliponase alfa), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being treated for a diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) documented by deficient tripeptidyl peptidase 1 (TPP1) enzyme activity or mutations in the CLN2/TPP1 gene

AND

2. Is 3 years of age or older

AND

3. Has documentation of a baseline CLN2 Clinical Rating Scale score

AND

4. Is prescribed Brineura (cerliponase alfa) by or in consultation with a pediatric neurologist

AND

5. Is prescribed a dose consistent with FDA-approved package labeling for the diagnosis

AND

6. Will be administered Brineura (cerliponase alfa) in accordance with FDA-approved package labeling

AND

7. Does not have a contraindication to Brineura (cerliponase alfa)

OR

8. The beneficiary does not meet the clinical review guidelines above, but in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary

FOR RENEWALS OF PRESCRIPTIONS FOR BRINEURA (CERLIPONASE ALFA): Requests for prior authorization of renewals of prescriptions for Brineura (cerliponase alfa) that were previously approved will take into account whether the beneficiary:

1. Is prescribed Brineura (cerliponase alfa) by or in consultation with a pediatric neurologist

AND

2. Has documentation of a repeat CLN2 Clinical Rating Scale score

AND

3. Based on the prescriber's professional judgment, continues to benefit from Brineura (cerliponase alfa)

AND

4. Is prescribed a dose consistent with FDA-approved package labeling for the diagnosis

AND

5. Will be administered Brineura (cerliponase alfa) in accordance with FDA-approved package labeling

AND

6. Does not have a contraindication to Brineura (cerliponase alfa)

OR

7. Does not meet the clinical review guidelines above, but in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of the request for a prescription for Brineura (cerliponase alfa). If the guidelines in Section B are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Brineura (cerliponase alfa) will be approved as follows:

1. The initial prescription will be approved for a period of up to six (6) months.

2. Renewals of prescriptions that were previously approved will be approved for a period of up to 12 months.

References

1. Brineura [prescribing information]. Novato, CA, BioMarin Pharmaceuticals, Inc.; April 2017.
2. Williams RE, Adams HR, Blohm M, et al. Management Strategies for CLN2 Disease. *Pediatr Neurol*. 2017 Apr;69:102-112.
3. http://www.cln2connection.com/overview/cln2-disease. Accessed July 28, 2017.
4. https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Batten-Disease-Fact-Sheet. Accessed July 28, 2017.
5. Brineura: EPAR Product information. BioMarin Pharmaceuticals, Inc.; June 2017
6. A Safety, Tolerability, and Efficacy Study of Intracerebroventricular BMN 190 in Pediatric Patients < 18 Years of Age With CLN2, Disease. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT02678689 Accessed September 11, 2017.
7. Center for Drug Evaluation and Research application number: 761052Orig1s000 Summary Review.