TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Cerliponase alfa (Brineura)	**CRITERIA ID:** TX.CC.PHAR.19
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy, Medical Directors
EFFECTIVE DATE: 03/15/2024	**PRODUCT(S):** STAR, STAR Health, STAR Kids, Star Plus, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 02/26/2025, 02/28/2025	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for cerliponase alfa (Brineura).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria, but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

This medication is a non-risk based (NRB) payment drug and should follow state guidance for medical necessity review for Medicaid/CHIP due to the manner in which it is reimbursed. All determinations will be performed by a Medical Director. A pharmacy clinician will review the prior authorization request and make a recommendation to the Medical Director but will not make the ultimate determination on any case.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS: N/A

POLICY:
It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of cerliponase alfa (Brineura); procedure code: J0567.

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. FDA Approved Indications

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. Prior authorization approval for Brineura (cerliponase alfa) will be considered when the following criteria are met (a and b):
    a. A request for the specific enzyme replacement therapy
    b. The laboratory evidence of the enzyme deficiency. See Appendix A with for examples of applicable diagnostic confirming labs.
3. Listed below are the FDA approved indication(s), age restrictions and diagnosis code(s) (as applicable):

a. Cerliponase alfa (Brineura) is indicated to slow the loss of ambulation in pediatric clients with late neuronal ceroid lipofuscinosis type 2 (CLN2). Diagnosis code: E75.4.

Approval duration: 6 months

Appendix A.

Enzyme replacement therapy	Indication	Diagnostic Lab Examples
Cerliponase alfa (Brineura)	Late infantile neuronal ceroid lipofuscinosis type 2 (CNL2)	TPP1 enzyme activity test demonstrating deficient TPP1 enzyme activity in leukocytes AND identification of 2 pathogenic mutations in trans in the TPP1/CLN2 gene

REFERENCES:
Texas Medicaid Provider Procedure Manual: Outpatient Drug Services Handbook

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy	Created TX.CC.PHAR.19; Brineura criteria taken from TX.CC.PHAR.33 Updated to TX.CC.PHAR format template Added Centene copyright statement Created separate criteria for Brineura ERT (from TX.CC.PHAR.33) to address Brineura NRB status	3/15/2024
Annual Review	No Changes	02/26/2025
Ad Hoc Review	Updated I.3.a. to align with TMHP CAD Manual verbiage effective 3/1/25	02/28/2025