Overview

Brineura (cerliponase alfa) is a hydrolytic lysosomal N-terminal tripeptidyl peptidase indicated to slow the loss of ambulation in symptomatic pediatric patients 3 years of age and older with late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency.

FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy. All other indications are considered experimental/investigational and are not a covered benefit. the member has no exclusions to the prescribed therapy.

Coverage Guidelines

Authorization may be granted for Brineura when all the following criteria are met, and clinical documentation has been submitted:

1. Documented diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), confirmed by TPP1 deficiency or genetic testing
2. The prescribing provider is a neurologist
3. The member is at least 3 years of age

Continuation of Therapy

Reauthorizations may be approved when documentation is submitted that initial criteria have been met.

Limitations

1. Initial approvals will be for 6 months.
2. Reauthorizations will be for 6-month intervals
References


Review History
04/17/19 – Reviewed

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