Commercial/Healthcare Exchange PA Criteria

Effective: May 11, 2023

Prior Authorization: Daybue (trofinetide)

Products Affected: Daybue (trofinetide) oral solution

Medication Description: DAYBUE is indicated for the treatment of Rett syndrome (RTT) in adults and pediatric patients 2 years of age and older.

Covered Uses:

1. Treatment of Rett syndrome in adults and pediatric patients 2 years of age and older.

Exclusion Criteria: None

Required Medical Information:

1. Patient Medical History

Prescriber Restriction: Medication must be prescribed by**,** or in consultation with**,** a neurologist experienced in the management of RTT

Age Restriction: 2 years of age or older

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

1. Classic or Typical Rett's Syndrome (RTT)

A. Patient is ≥2 years of age; **AND**
B. Patient's weight is ≥12 kg; **AND**
C. Patient has confirmed mutation of the MECP2 gene; **AND**
D. Patient has classic/typical Rett syndrome, according to the Rett Syndrome Diagnostic Criteria**; AND**

Note: The diagnosis of classic/typical Rett syndrome requires all main diagnostic criteria and none of the exclusion criteria. The main Rett syndrome diagnostic criteria are: 1) partial or complete loss of acquired purposeful hand skills; 2) partial or complete loss of acquired spoken language; 3) gait abnormalities, i.e., impaired (dyspraxic) or absence of ability; and 4) stereotypic hand movements, such as hand wringing/squeezing, clapping/tapping, mouthing and washing/rubbing automatisms. The exclusion criteria for classic/typical Rett syndrome are: 1) brain injury secondary to trauma (peri- or postnatally), neurometabolic disease, or severe infection that causes neurological problems; and 2) grossly abnormal psychomotor development in first 6 months of life.

E. According to the prescriber, patient is past the initial period of regression (i.e., no additional loss or degradation in ambulation, hand function, speech, or nonverbal communicative or social skills within 6 months of initial period of regression); **AND**

F. Requested medication is prescribed by, or in consultation with, a neurologist experienced in the management of RTT

References:

1. Product Information: DAYBUE™ oral solution, trofinetide oral solution. Acadia Pharmaceuticals Inc (per FDA), San Diego, CA, 2023.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	05/11/2023