Mass General Brigham
Health Plan

Daybue (trofinetide)
Effective 11/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
Daybue (trofenitide) is indicated for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older.

Coverage Guidelines
Authorization may be reviewed for members new to the plan within the last 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted when all of the following criteria are met:

1. Member has a diagnosis of Rett Syndrome
2. Documentation confirming diagnosis by a mutation in the MECP2 gene
3. Documentation that member exhibits clinical manifestations of disease (e.g., hand wringing, apraxia, gait abnormalities, development delays)
4. Member is 2 years of age or older

Continuation of Therapy
Requests for reauthorization will be approved when the following criteria are met:

1. Member is experiencing benefit from therapy (e.g., stabilization or improvement in repetitive movements, mood dysfunction/disruptive behavior, vocalization, ambulation).

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.
2. The following quantity limits apply:

Drug Name and Dosage Form	Quantity Limit
Daybue oral solution	120 mL per day

References

1. Daybue (trofinetide) [prescribing information]. San Diego, CA: Acadia Pharmaceuticals, Inc.; September 2024.

2. Neul JL, Percy AK, Benke TA, et al. Design and outcome measures of LAVENDER, a phase 3 study of trofinetide for Rett syndrome. Contemp Clin Trials. 2022;114:106704.
3. Neul JL, Eskind AS. Rett syndrome: NORD. National Organization for Rare Disorders. https://rarediseases.org/rare-diseases/rett-syndrome/#complete-report Published March 15, 2023. Accessed March 16, 2023.

Review History
07/12/2023 - Reviewed at July P&T, Effective 9/1/23.
08/13/2025 – Reviewed and updated at August P&T. Updated language for members who are new to the Plan. Updated verbiage from “medical records” to “documentation” and added quantity limits to the Limitations section of the policy. Effective 11/01/2025.