Mass General Brigham
Health Plan

# Daybue (trofinetide)
# Effective 09/01/2023

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| **Plan** | ☐ MassHealth UPPL<br>☒Commercial/Exchange | **Program Type** | ☒ Prior Authorization<br>☐ Quantity Limit<br>☐ Step Therapy |
| **Benefit** | ☒ Pharmacy Benefit<br>☐ Medical Benefit | | |
| **Specialty Limitations** | This medication has been designated specialty and must be filled at a contracted specialty pharmacy. | | |
| **Contact Information** | **Medical and Specialty Medications**<br>All Plans \| Phone: 877-519-1908 \| Fax: 855-540-3693 | | |
| | **Non-Specialty Medications**<br>All Plans \| Phone: 800-711-4555 \| Fax: 844-403-1029 | | |
| **Exceptions** | N/A | | |

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

**Coverage Guidelines**
Authorization may be granted for members new to General Brigham Health Plan who are currently receiving treatment with Daybue excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
**OR**
Authorization may be granted for members meeting ALL the following criteria:

1. Member has a diagnosis of Rett Syndrome
2. Medical records confirming diagnosis by a mutation in the MECP2 gene
3. Medical records 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**
Authorization of 12 months may be granted for continued treatment of Rett syndrome in members who are experiencing benefit from therapy (e.g., stabilization or improvement in repetitive movements, mood dysfunction/disruptive behavior, vocalization, ambulation).

**Limitations**
Initial approvals and reauthorizations will be granted for 12 months.

**References**

1. Daybue [package insert]. San Diego, CA: Acadia Pharmaceuticals, Inc.; March 2023.
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