Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Daybue™ (trofinetide)

Effective: February 1, 2024

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

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

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Daybue for Members when all of the following criteria are met:

Initial Authorization Criteria

1. Documentation of classic (or typical) Rhett syndrome consistent with the RettSearch Consortium diagnostic criteria

AND

2. Documentation the patient does not have atypical or variant Rett Syndrome

AND

3. The patient is at least 2 years of age

AND

4. Prescribed by a neurologist or pediatric specialist with expertise in Rett Syndrome

AND

5. Documentation of mutation on the MECP2 gene

AND

6. Clinical Global Impression-Severity score of at least 4

Reauthorization Criteria

1. Documentation of classic (or typical) Rhett syndrome consistent with the RettSearch Consortium diagnostic criteria

AND

2. Documentation the patient does not have atypical or variant Rett Syndrome

AND

3. The patient is at least 2 years of age

AND

4. Prescribed by or in consultation with a neurologist or a pediatric specialist with expertise in this disease

AND

5. Documentation the patient is responding positively to therapy as evidenced by a stabilization or improvement in Clinical Global Impression-Improvement score

Limitations

1. Initial coverage of Daybue will be authorized for 6 months. Reauthorization of Daybue will be provided in 12-month intervals.
2. Members new to the plan stable on Daybue should be reviewed against Reauthorization Criteria.

Codes

None

References

1. Fu C, et al. Consensus guidelines on managing Rett syndrome across the lifespan. BMJ Paediatrics Open. 2020;4:e000717.
2. Neul JL, et al. Rett Syndrome: Revised Diagnostic Criteria and Nomenclature. Ann Neurol. 2010 Dec; 86(6):944-50.
3. Daybue (trofinetide) [prescribing information]. San Diego, CA: Acadia Pharmaceuticals Inc.; 2023 March.

Approval And Revision History

July 11, 2023: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- January 9, 2024: For Reauthorization Criteria, updated requirement for documentation of stabilization or improvement based on the Clinical Global Impression-Improvement score (effective 2/1/2024).

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.