

Pharmacy Medical Necessity Guidelines: Evrysdi™ (risdiplam)

Effective: January 18, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p>Commercial Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – small group plans • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>Tufts Health Public Plans Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan 		<p>Fax Numbers:</p> <p>RXUM: 617.673.0988</p>	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Evrysdi (risdiplam) is a survival of motor neuron 2 (SMN2) splicing modifier indicated for the treatment of spinal muscular atrophy (SMA) in patients 2 months of age and older.

COVERAGE GUIDELINES

The plan may authorize coverage of Evrysdi (risdiplam) for Members, when all of the following criteria are met:

Initial Authorization

1. The Member is at least 2 months of age
AND
2. Documented diagnosis of spinal muscular atrophy type 1, 2, or 3 confirmed by molecular genetic testing of any of the following: SMN1 homozygous gene deletion, homozygous conversion mutation (i.e., SMN1 gene conversion to SMN2 gene), or compound heterozygote mutation
AND
3. Prescribed by or written in consultation with a board-certified neurologist with special qualification in child neurology and treatment of spinal muscular atrophy
AND
4. Documentation of baseline (pre-treatment) motor function skills
AND
5. The Member is not using Evrysdi concomitantly with Spinraza
AND
6. Documentation of one of the following:
 - a. The Member has not previously received gene replacement therapy for the treatment of SMA
 - b. The Member has previously received gene replacement therapy for the treatment of SMA and has experienced a decline in clinical status since receipt of gene replacement therapy**AND**
7. Documentation Member is not ventilation dependent (defined as using a ventilator 16 hours or more a day)

Reauthorization Criteria

1. The Member is at least 2 months of age
AND
2. Documented diagnosis of spinal muscular atrophy type 1, 2, or 3 confirmed by molecular genetic testing
AND

3. Prescribed by or written in consultation with a board-certified neurologist with special qualification in child neurology and treatment of spinal muscular atrophy
AND
4. The Member is not using Evrysdi concomitantly with Spinraza
AND
5. Documentation of one of the following:
 - a. The Member has not previously received gene replacement therapy for the treatment of SMA
 - b. The Member has previously received gene replacement therapy for the treatment of spinal muscular atrophy and has experienced a decline in clinical status since receipt of gene replacement therapy
- AND**
6. Documentation Member is not ventilation dependent (defined as using a ventilator 16 hours or more a day)
AND
7. Documentation of disease stabilization or clinical improvement of SMA symptoms (e.g., limb and trunk weakness; hypotonia and impaired head control; difficult breathing, swallowing, feeding, and handling secretions)

LIMITATIONS

- Coverage of Evrysdi (risdiplam) for SMA type 4 will not be authorized.
- Authorizations will be provided for 12 months.
- Members new to the plan stable on Evrysdi (risdiplam) should be reviewed against Initial Authorization Criteria. For treatment-experienced Members, Providers must submit documentation of a physical assessment, motor function-based testing, and need for medical intervention related to SMA symptoms, relative to baseline.
- If gene therapy is subsequently administered, Evrysdi (risdiplam) authorization will be terminated and the Member must reapply for coverage.

CODES

None

REFERENCES

1. Evrysdi (risdiplam) [prescribing information]. South San Francisco, CA: Genentech, Inc.; 2020 August.
2. Mercuri E, Barisic N, Boespflug-Tanguy O et al. SUNFISH part 2: efficacy and safety of risdiplam (RG7916) in patients with type 2 or non-ambulant type 3 spinal muscular atrophy (SMA). Poster presented at 2020 American Academy of Neurology Annual Meeting. Abstract 11-010.
3. Mercuri E, Finkel RS, Muntoni F et al. Diagnosis and management of spinal muscular atrophy: Part 1: Recommendations for diagnosis, rehabilitation, orthopedic and nutritional care. *Neuromuscul Disord.* 2018; 28(2): 103-15.
4. Servais L, Baranello G, Masson R et al. FIREFISH part 2: efficacy and safety of risdiplam (RG7916) in Infants with type 1 spinal muscular atrophy (SMA). Poster presented at 2020 American Academy of Neurology Annual Meeting. Abstract 11-011.
5. Wang CH, Finkel RS, Bertini ES, et al. Consensus statement for standard of care in spinal muscular atrophy. *J Child Neurol.* Aug 2007;22(8):1027-49.

APPROVAL HISTORY

December 8, 2020: Reviewed by Pharmacy & Therapeutics Committee.

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.