BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Evrysdi

Policy Number: 9.232
Revision Number: 1.0
Version Effective Date: 9/1/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth- MCO ☒ MassHealth- ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Evrysdi(risdiplam)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All medically excepted indications unless otherwise excluded
Required Medical Information	1. Diagnosis of spinal muscular atrophy type 1, 2, or 3; **AND** 2. Genetic testing confirming one of the following (documentation required): • Homozygous deletion of the SMN 1 gene • Homozygous mutation in the SMN 1 gene • Compound heterozygous mutation in the SMN1gene; **AND** 3. One of the following: • If SMA type 1, member has two copies of SMN2 (medical records required)

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	• If SMA type 2 or 3, member is non ambulatory; **AND** 4. Documentation of baseline motor function test from one or more of the following: a. Hammersmith Infant Neurologic Exam (HINE) b. Hammersmith Functional Motor Scale Expanded (HFMSE) c. 6-minute walk test (6MWT) d. Upper limb module (ULM) e. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP _INTEND); **AND** 5. Member does not require tracheostomy or invasive ventilation; **AND** 5. Dose does not exceed 5mg per day; **AND** 6. Member will not receive Ervysdi concurrently with Spinraza and/or Zolgensma; **AND** 7. Member has not previously received Zolgensma
Age Limit	2 months of age or older
Prescriber Restriction	Prescribed by or in consultation with a neurologist, neuromuscular specialist or in consultation with a neurologist with expertise in the diagnosis of spinal muscular atrophy
Coverage Duration	Initial: 6 months Reauthorization: 12 months
Other criteria	1. Medical records (within the past three months) documenting positive response to therapy as shown by improvement in the motor function tests or stability of function based on the following tests: a. Hammersmith Infant Neurologic Exam (HINE) b. Hammersmith Functional Motor Scale Expanded (HFMSE) c. 6-minute walk test (6MWT) d. Upper limb module (ULM) **e.** Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP _INTEND); **AND** 2. Member does not require tracheostomy or invasive ventilation; **AND** 3. Dose does not exceed 5mg per day; **AND** 4. Member will not receive Ervysdi concurrently with Spinraza and/or Zolgensma

Clinical Background Information and References

1. Evrysdi (risdiplam) [prescribing information]. San Francisco, CA. Genentech, Inc. August 2020

Original Approval Date	Original Effective Date	Policy Owner	Approved by
5/13/2021	9/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
5/13/2021	Policy created	9/1/2021	P&T Committee

Next Review Date

2/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.