JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS132
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	Subject **Evrysdi**	*Revision Date*	12/08/2021
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Evrysdi, risdiplam

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I. POLICY

Evrysdi (risdiplam) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Evrysdi** may be approved for patients meeting all the following:
   1. Patient is 2 months of age or older
   2. Documented diagnosis of Spinal Muscular Atrophy (SMA) Type 1, 2, or 3
   3. Documentation confirming diagnosis by FDA approved genetic diagnostic testing, consisting of both of the following:
      a. Patient has at least two copies of survival motor neuron 2 (SMN2)
      b. Testing of 5q SMA showing one of the following;
         I. Homozygous gene deletion
         II. Homozygous conversion mutation
         III. Compound heterozygote
   4. Patient is not dependent on invasive ventilation or tracheostomy
   5. Patient has documented signs and symptoms associated with SMA (such as muscle weakness, limited mobility, delayed gross motor skills, difficulty breathing, etc.)
   6. Patient will not be treated with another therapy used for SMA (Spinraza, Zolgensma, etc.)
   7. Prescriber is a neurologist with expertise in treating SMA

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial therapy may be approved for 12 months

B. Continuation of therapy may be approved in 12-month intervals with documentation showing the patient has had a beneficial response to treatment, evidenced by both of the following:
   1. Patient still does not require invasive ventilation, and has experienced one of the following:
      1. Reduced decline in motor function
      2. Improvement in motor function
      3. Stabilization of condition

IV. EXCLUSIONS

A. Evrysdi will not be approved for the following:
   1. Concomitant use with another chronic survival motor neuron (SMN) modifying therapy (e.g. Spinraza [nusinersen]), or gene replacement therapy (e.g. Zolgensma [onasemnogene abeparvovec-xioi]) used for treatment of SMA
   2. Any indications or uses that are not FDA-approved, or guideline-supported

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Evrysdi [prescribing information]. South San Francisco, CA: Genentech, Inc; August 2020

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
01/20/2021	Policy Creation
12/08/2021	Updated Exclusions section regarding physician samples

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