Reference number(s)
4096-A

STANDARD MEDICARE PART B MANAGEMENT

EVRYSDI (risdiplam)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Evrysdi is indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all initial submissions: Deletion or mutation at the SMN1 allele confirmed by genetic testing

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a physician who specializes in treatment of spinal muscular atrophy.

IV. CRITERIA FOR INITIAL APPROVAL

Spinal muscular atrophy (SMA)
Authorization of 12 months may be granted for treatment of SMA when all of the following criteria are met:
A. Member has a diagnosis of SMA confirmed by genetic testing showing deletion or mutation at the SMN1 allele.
B. Member has Type 1, Type 2 or Type 3 SMA.
C. Member will not use Evrysdi and Spinraza concomitantly.

V. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with Evrysdi.
B. Evrysdi is being used to treat an indication enumerated in Section IV.
C. The member is receiving benefit from therapy.
D. Member will not use Evrysdi and Spinraza concomitantly.

VI. REFERENCES

1. Evrysdi [package insert]. South San Francisco, CA: Genentech, Inc; May 2022.