STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RISDIPLAM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RISDIPLAM	EVRYSDI	46765		GPI-10 (7470656000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of spinal muscular atrophy (SMA) and meet **ALL** of the following criteria?
   - Diagnosis of spinal muscular atrophy (SMA) is confirmed by documentation of gene mutation analysis indicating mutations or deletions of both alleles of the survival motor neuron 1 (SMN1) gene (e.g., homozygous deletions of SMN1, homozygous mutations of SMN1, compound heterozygous mutations in SMN1 [i.e., deletion of SMN1 on one allele and point mutation of SMN1 on the other allele])
   - Therapy is prescribed by or given in consultation with a neuromuscular specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient presymptomatic **AND** meets the following criterion?
   - There is documentation of up to (i.e., no more than) three copies of survival motor neuron 2 (SMN2) based on newborn screening

   If yes, **approve for 12 months by HICL or GPI-10 for #240mL per 30 days.**
   APPROVAL TEXT: Renewal requires that the patient has improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline, OR in other muscle function.

   If no, continue to #3.

CONTINUED ON NEXT PAGE

RISDIPLAM

INITIAL CRITERIA (CONTINUED)

3. Is the patient symptomatic and meets **ALL** of the following criteria?
   - The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age
   - There is documentation of a baseline motor function assessment by a neuromuscular specialist or SMA specialist
   - For patients who have received prior gene therapy: the patient had less than expected clinical benefit with gene therapy

   If yes, **approve for 12 months by HICL or GPI-10 for #240mL per 30 days.**
   APPROVAL TEXT: Renewal requires that the patient has improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline, OR in other muscle function.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RISDIPLAM (Evrysdi)** requires the following rule(s) be met for approval:
   A. You have spinal muscular atrophy (SMA: genetic disorder where your muscles become weak and break down)
   B. Your diagnosis of spinal muscular atrophy (SMA) is confirmed by documentation of a gene mutation analysis indicating mutations or deletions of both alleles of the survival motor neuron 1 (SMN1: type of protein in spinal cord) gene (such as homozygous deletions of SMN1, homozygous mutations of SMN1, compound heterozygous mutations in SMN1 [deletion of SMN1 on one allele and point mutation of SMN1 on the other allele])
   C. The requested medication is prescribed by or given in consultation with a neuromuscular (nerve and muscle) specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
   D. **If you are presymptomatic (symptoms have not yet appeared), approval also requires:**
      1. There is documentation showing you have up to three copies of survival motor neuron 2 (SMN2: type of protein in spinal cord) based on screening done when you were a newborn
   E. **If you are symptomatic (symptoms have appeared), approval also requires:**
      1. The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age
      2. There is documentation showing you had a baseline motor function assessment by a neuromuscular (nerve and muscle) specialist or SMA specialist
      3. If you previously had gene therapy, you had less than expected clinical benefit

   (Initial denial text continued on the next page)

CONTINUED ON NEXT PAGE

RISDIPLAM

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of spinal muscular atrophy (SMA) and meet **ONE** of the following criteria?
   - The patient has improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline (e.g., HINE, HFMSE, CHOP-INTEND)
   - The patient has improved, maintained, or demonstrated less than expected decline in other muscle function (e.g., pulmonary)

   If yes, **approve for 12 months by HICL or GPI-10 for #240mL per 30 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RISDIPLAM (Evrysdi)** requires the following rule(s) be met for renewal:
   A. You have spinal muscular atrophy (SMA: genetic disorder where your muscles become weak and break down)
   B. You meet ONE of the following:
      1. You have improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline. Some types of motor assessment tests include Hammersmith Infant Neurological Examination (HINE), Hammersmith Functional Motor Scale - Expanded (HFMSE) and Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
      2. You have improved, maintained, or demonstrated less than expected decline in other muscle function such as pulmonary (lung/breathing) function

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RISDIPLAM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Evrysdi.

REFERENCES

- Evrysdi [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/21/20

Created: 08/20
Client Approval: 04/20

P&T Approval: 04/20