Texas Prior Authorization Program
Clinical Criteria

Drug/Drug Class

Evrysdi (Risdiplam)

Clinical Information Included in this Document

- **Drugs requiring prior authorization**: the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic**: a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram**: a visual depiction of the clinical criteria logic
- **Supporting tables**: a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes); provided when applicable
- **References**: clinical publications and sources relevant to this clinical criteria

Note: Click the hyperlink to navigate directly to that section.

Revision Notes

Initial publication and presentation to the DUR Board

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Drugs Requiring Prior Authorization

The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.

Drugs Requiring Prior Authorization	
Label Name	**GCN**
EVRYSDI 60 MG/80 ML (0.75 MG/ML)	48456

RxPERT PAXPRESS

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Clinical Criteria Logic

Initial Prior Authorization Request (Manual Review):

1. Is the medication being prescribed by, or in conjunction with, a neurologist or pediatrician specializing in the treatment of spinal muscular atrophy?
   [ ] Yes (Go to #2)
   [ ] No (Deny)

2. Does the client have a **diagnosis of spinal muscular atrophy (SMA)** in the last 730 days? (**Supporting documentation** must be provided along with baseline motor function tests)
   [ ] Yes (Go to #3)
   [ ] No (Deny)

3. Will the client have concurrent therapy with Spinraza (nusinersen) or Zolgensma (onasemnogene abeparvovec) or has the client had prior therapy with Zolgensma (onasemnogene abeparvovec)?
   [ ] Yes (Deny)
   [ ] No (Go to #3)

4. Does the client have advanced SMA (ventilator dependence > 16 hours/day or tracheostomy)?
   [ ] Yes (Deny)
   [ ] No (Go to #5)

5. Has the client been hospitalized for a pulmonary event in the last 60 days?
   [ ] Yes (Deny)
   [ ] No (Go to #6)

6. Has the client had surgery for scoliosis in the last 365 days?
   [ ] Yes (Deny)
   [ ] No (Go to #7)

7. Is the requested dose less than or equal to (≤) 5mg per day?
   [ ] Yes (Approve – 365 days)
   [ ] No (Deny)

Renewal Requests (Manual Review):

1. Does the client have advanced SMA (permanent ventilator dependence or tracheostomy)?
   [ ] Yes (Deny)
   [ ] No (Go to #2)

2. Has the client had a positive response to treatment, demonstrated by clinical improvement or no decline in function? (**Supporting documentation** must be provided comparing baseline functional scores to current scores)
   [ ] Yes (Approve – 365 days)
   [ ] No (Deny)

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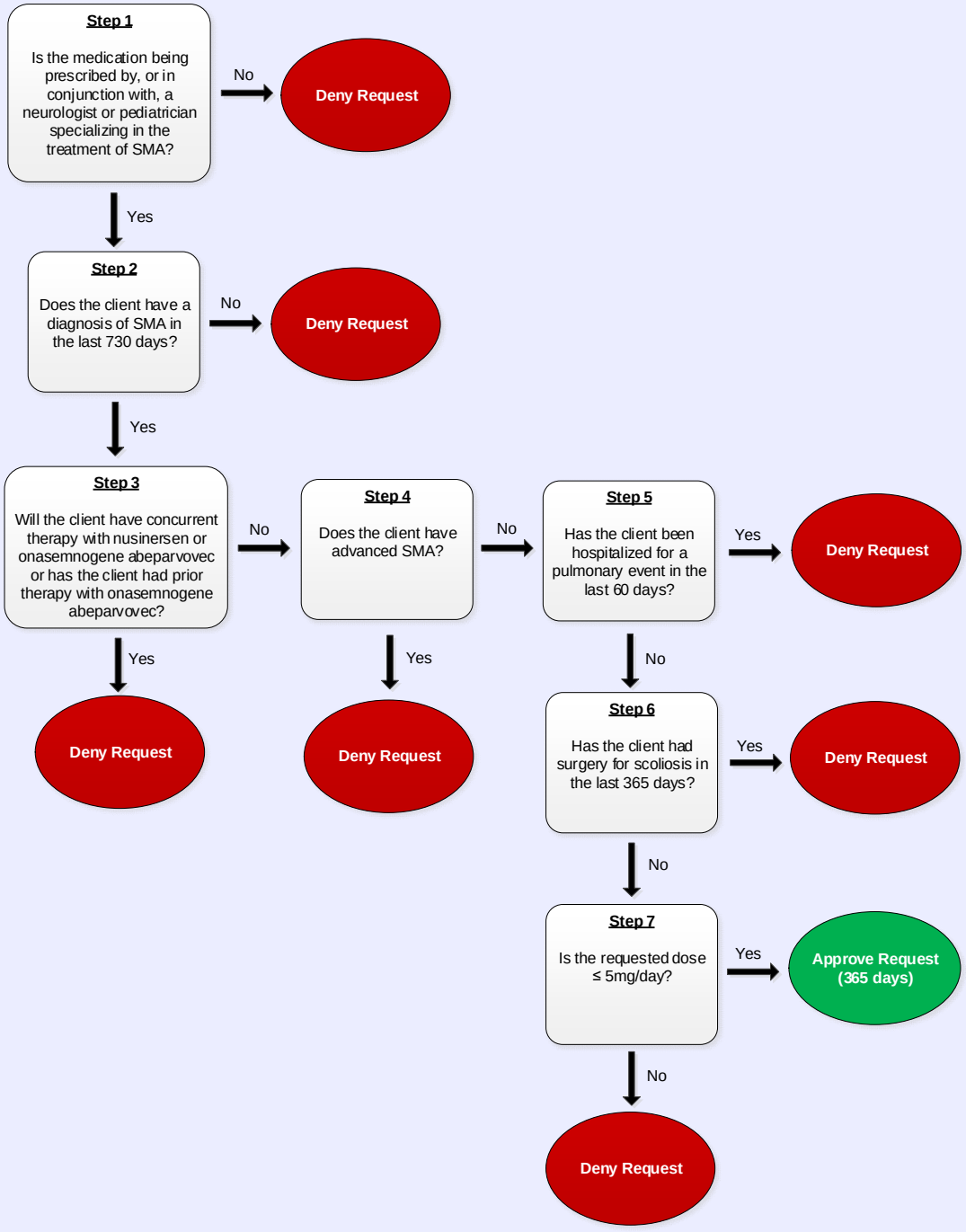
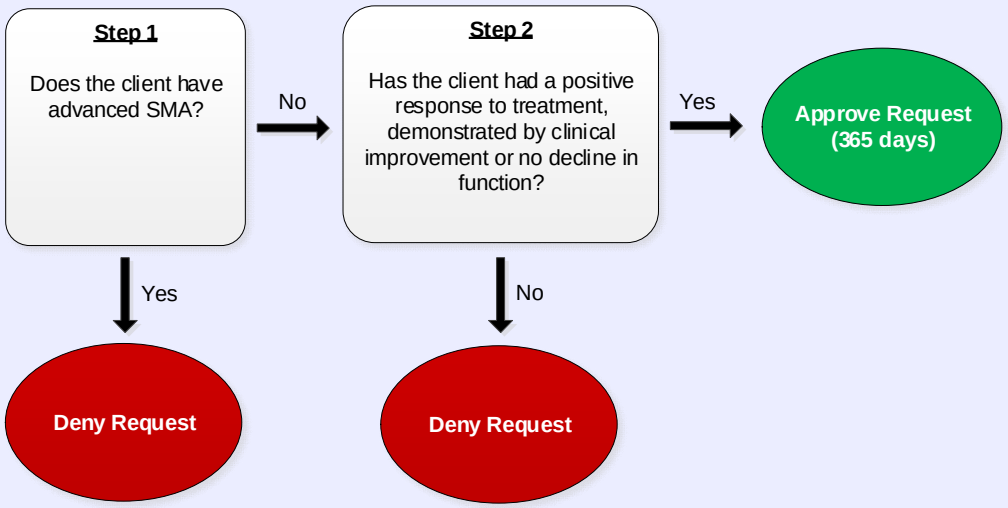
Clinical Criteria Logic Diagram

Initial Prior Authorization:



Refill Request:



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Clinical Criteria Supporting Tables

Step 2 (diagnosis of spinal muscular atrophy) **Required diagnosis:** *1* **Look back timeframe:** *730 days*	
ICD-10 Code	**Description**
G120	INFANTILE SPINAL MUSCULAR ATROPHY, TYPE I [WERDNIG-HOFFMAN]
G121	OTHER INHERITED SPINAL MUSCULAR ATROPHY
G1220	MOTOR NEURON DISEASE UNSPECIFIED
G1221	AMYOTROPHIC LATERAL SCLEROSIS
G1222	PROGRESSIVE BULBAR PALSY
G1223	PRIMARY LATERAL SCLEROSIS
G1224	FAMILIAL MOTOR NEURON DISEASE
G1225	PROGRESSIVE SPINAL MUSCLE ATROPHY
G1229	OTHER MOTOR NEURON DISEASE
G128	OTHER SPINAL MUSCULAR ATROPHIES AND RELATED SYNDROMES
G129	SPINAL MUSCULAR ATROPHY, UNSPECIFIED

Supporting Documentation for Evrysdi (risdiplam)
Initial Request: Diagnosis of spinal muscular atrophy (SMA), confirmed by SM1 gene mutation or deletion Initial/Renewal Request: Testing tools that can be used to demonstrate physical function include, but are not limited to: • The Hammersmith Infant Neurological Exam (HINE) • The Hammersmith Functional Motor Scale Expanded (HFSME) • The Upper Limb Module (UML) or revised Upper Limb Module (RULM) • Baseline 6MWT • Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)

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Clinical Criteria References

1. 2020 ICD-10-CM Diagnosis Codes. 2020. Available at **www.icd10data.com**. Accessed on October 23, 2020.
2. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2020. Available at **www.clinicalpharmacology.com**. Accessed on October 23, 2020.
3. Micromedex [online database]. Available at **www.micromedexsolutions.com**. Accessed on October 23, 2020.
4. Evrysdi Prescribing Information. South San Francisco, CA. Genentech, Inc. August 2020.
5. Mercuri E, Darras BT, Chiriboga CA, et al. Nusinersen versus Sham Control in Later-Onset Spinal Muscular Atrophy. N Engl J Med 2018;378:625.

Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

Publication Date	Notes
10/23/2020	• Initial publication and presentation to the DUR Board