

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

Removed check for hepatic impairment



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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



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Clinical Criteria Logic

Initial Prior Authorization Request (Manual Review):

1. Does the client have a **diagnosis of spinal muscular atrophy (SMA) type 1, 2 or 3** in the last 730 days? (**Supporting documentation** must be provided along with baseline motor function tests)
 Yes (Go to #2)
 No (Deny)
2. Is the client less than (<) 65 years of age?
 Yes (Go to #3)
 No (Deny)
3. Is the client **pregnant**?
 Yes (Deny)
 No (Go to #4)
4. Is the requested dose less than or equal to (\leq) 5mg per day?
 Yes (Approve – 365 days)
 No (Deny)

Renewal Requests (Manual Review):

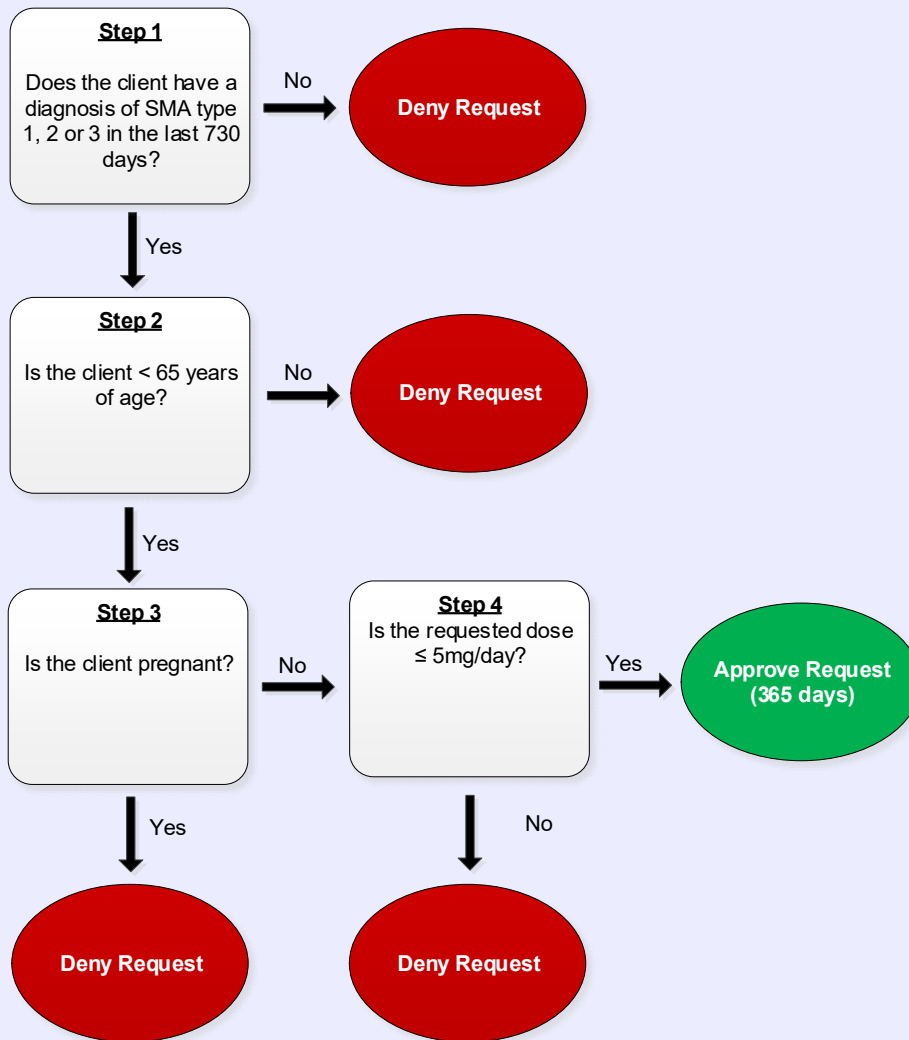
1. Is the client greater than (>) 65 years of age?
 Yes (Deny)
 No (And the client is female < 51 years of age, go to #2)
 No (And the client is male or female \geq 51 years of age, go to #3)
2. Is the client **pregnant**?
 Yes (Deny)
 No (Go to #3)
3. Has the client had a positive response to treatment, 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)



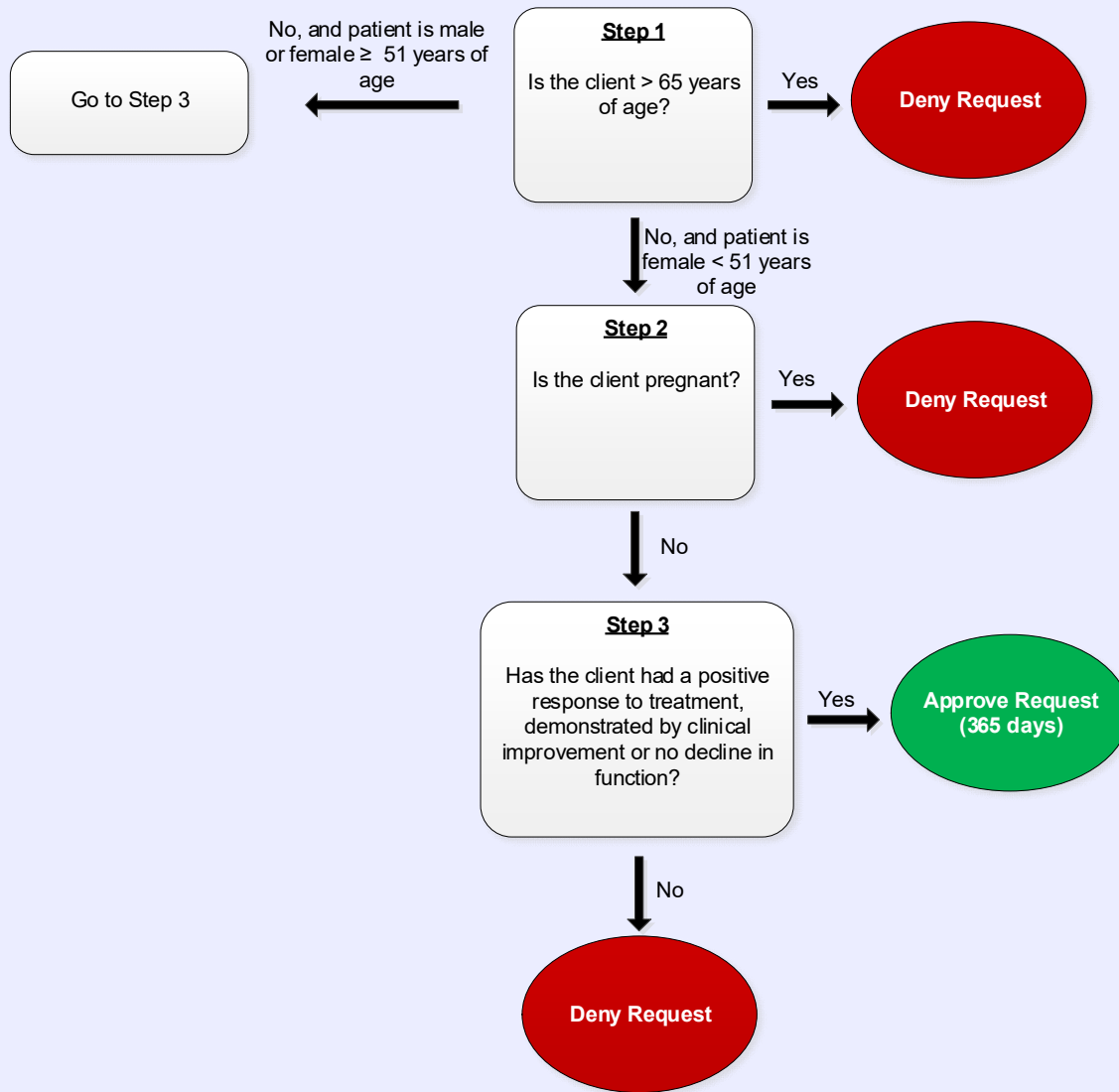
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Clinical Criteria Logic Diagram

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)
<p>Initial Request: Diagnosis of spinal muscular atrophy (SMA), confirmed by SM1 gene mutation or deletion</p> <p>Initial/Renewal Request: Testing tools that can be used to demonstrate physical function include, but are not limited to:</p> <ul style="list-style-type: none"> • 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)

Step 3 (diagnosis of Pregnancy)	
Required quantity: 1	
ICD-10 Code	Description
O3670X0	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, UNSPECIFIED TRIMESTER, NOT APPLICABLE OR UNSPECIFIED
O3670X1	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, UNSPECIFIED TRIMESTER, FETUS 1
O3670X2	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, UNSPECIFIED TRIMESTER, FETUS 2
O3670X3	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, UNSPECIFIED TRIMESTER, FETUS 3
O3670X4	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, UNSPECIFIED TRIMESTER, FETUS 4
O3670X5	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, UNSPECIFIED TRIMESTER, FETUS 5
O3670X9	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, UNSPECIFIED TRIMESTER, OTHER FETUS
O3671X0	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, FIRST TRIMESTER, NOT APPLICABLE OR UNSPECIFIED
O3671X1	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, FIRST TRIMESTER, FETUS 1
O3671X2	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, FIRST TRIMESTER, FETUS 2
O3671X3	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, FIRST TRIMESTER, FETUS 3
O3671X4	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, FIRST TRIMESTER, FETUS 4
O3671X5	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, FIRST TRIMESTER, FETUS 5
O3671X9	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, FIRST TRIMESTER, OTHER FETUS
O3672X0	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, SECOND TRIMESTER, NOT APPLICABLE OR UNSPECIFIED
O3672X1	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, SECOND TRIMESTER, FETUS 1
O3672X2	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, SECOND TRIMESTER, FETUS 2
O3672X3	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, SECOND TRIMESTER, FETUS 3
O3672X4	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, SECOND TRIMESTER, FETUS 4
O3672X5	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, SECOND TRIMESTER, FETUS 5
O3672X9	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, SECOND TRIMESTER, OTHER FETUS
O3673X0	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, THIRD TRIMESTER, NOT APPLICABLE OR UNSPECIFIED

Step 3 (diagnosis of Pregnancy) Required quantity: 1	
ICD-10 Code	Description
O3673X1	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, THIRD TRIMESTER, FETUS 1
O3673X2	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, THIRD TRIMESTER, FETUS 2
O3673X3	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, THIRD TRIMESTER, FETUS 3
O3673X4	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, THIRD TRIMESTER, FETUS 4
O3673X5	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, THIRD TRIMESTER, FETUS 5
O3673X9	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, THIRD TRIMESTER, OTHER FETUS



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Clinical Criteria References

1. 2020 ICD-10-CM Diagnosis Codes. 2021. Available at www.icd10data.com. Accessed on January 22, 2021.
2. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, August 5, 2024.
3. Micromedex [online database]. Available at www.micromedexsolutions.com. Accessed on August 5, 2024.
4. Evrysdi Prescribing Information. South San Francisco, CA. Genentech, Inc. February 2024.
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
01/22/2021	<ul style="list-style-type: none">Initial publication and presentation to the DUR Board
06/09/2022	<ul style="list-style-type: none">Updated age for Evrysdi to < 65 years in criteria logic
05/08/2024	<ul style="list-style-type: none">Annual review by staffUpdated references
08/05/2024	<ul style="list-style-type: none">Removed check for hepatic impairment