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

Evrysdi (Risdiplam)

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™

Evrysdi (Risdiplam)

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 between 2 months and 65 years of age?
   [ ] Yes (Go to #3)
   [ ] No (Deny)

3. Is the client **pregnant**?
   [ ] Yes (Deny)
   [ ] No (Go to #4)

4. Does the client have a **diagnosis of hepatic impairment**?
   [ ] Yes (Deny)
   [ ] No (Go to #5)

5. Is the requested dose less than or equal to (≤) 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 ≥ 51 years of age, go to #3

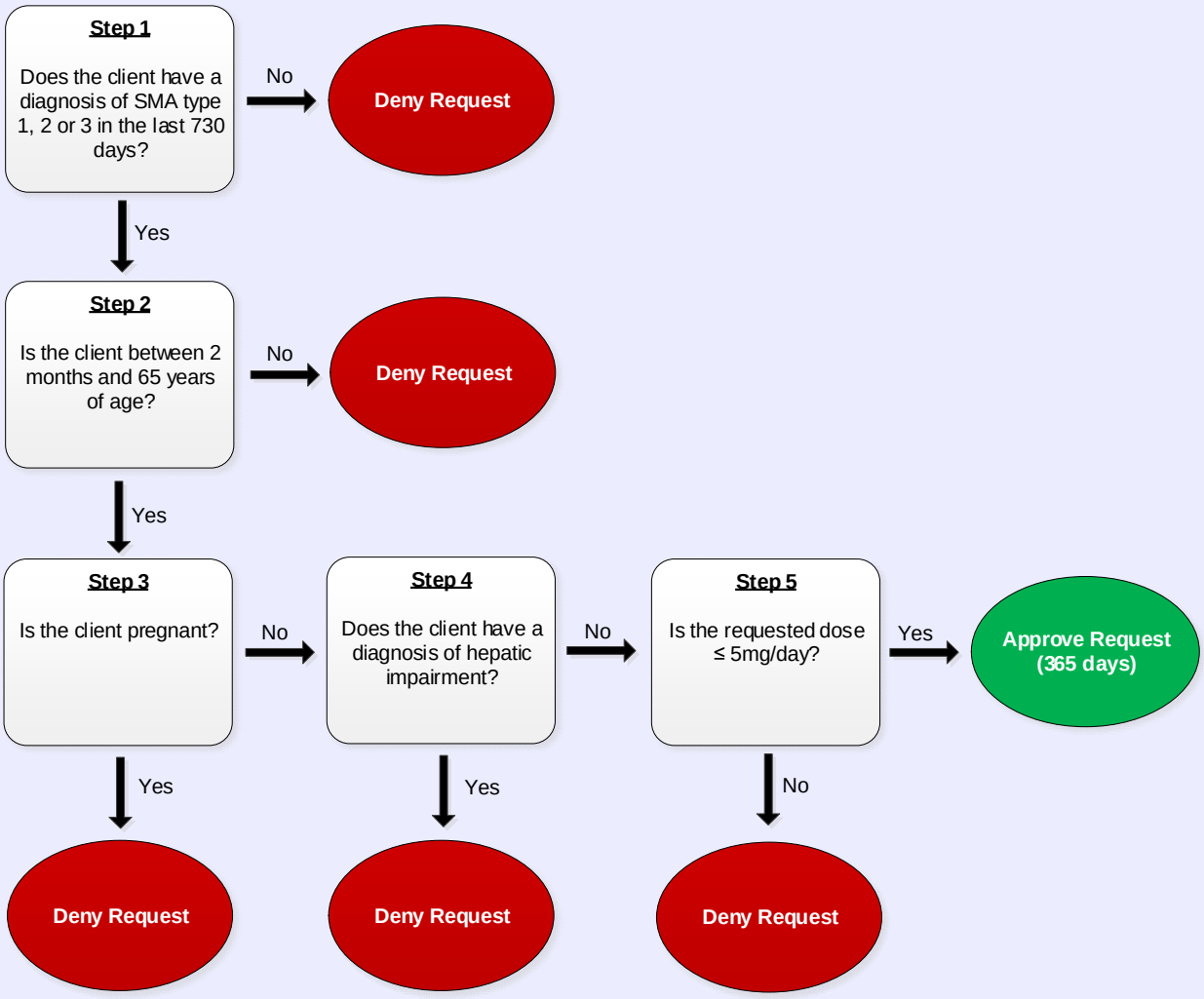
2. Is the client **pregnant**?
   [ ] Yes (Deny)
   [ ] No (Go to #3)

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)

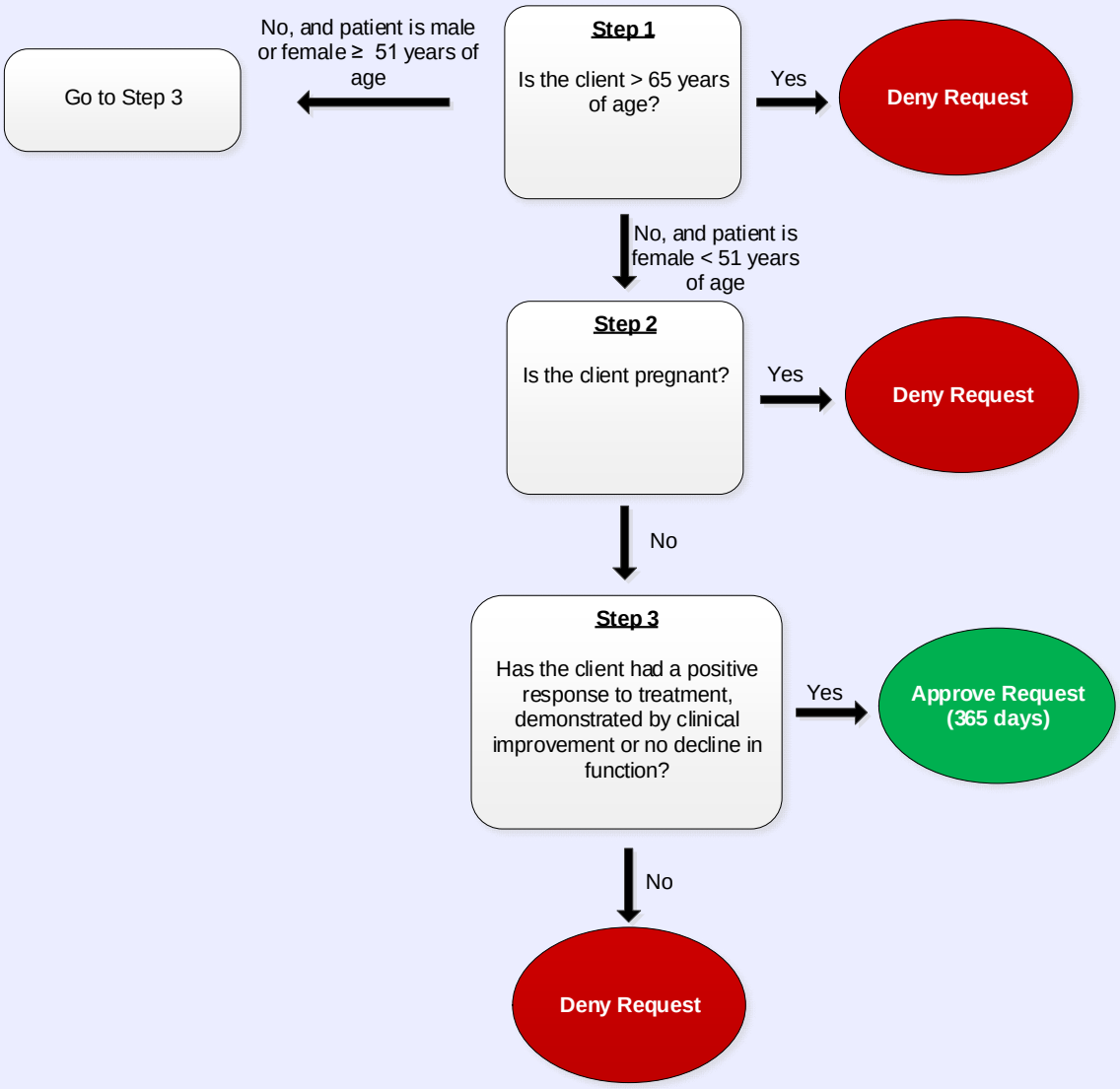
Evrysdi (Risdiplam)

Clinical Criteria Logic Diagram

Initial Prior Authorization:



Refill Request:



Evrysdi (Risdiplam)

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)

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

Step 4 (diagnosis of hepatic disease or hepatic impairment) **Required diagnosis:** *1* **Look back timeframe:** *365 days*	
ICD-10 Code	**Description**
B160	ACUTE HEPATITIS B WITH DELTA-AGENT WITH HEPATIC COMA
B161	ACUTE HEPATITIS B WITH DELTA-AGENT WITHOUT HEPATIC COMA
B162	ACUTE HEPATITIS B WITHOUT DELTA-AGENT WITH HEPATIC COMA
B169	ACUTE HEPATITIS B WITHOUT DELTA-AGENT AND WITHOUT HEPATIC COMA
B170	ACUTE DELTA-(SUPER) INFECTION OF HEPATITIS B CARRIER
B1710	ACUTE HEPATITIS C WITHOUT HEPATIC COMA
B1711	ACUTE HEPATITIS C WITH HEPATIC COMA
B172	ACUTE HEPATITIS E
B178	OTHER SPECIFIED ACUTE VIRAL HEPATITIS
B179	ACUTE VIRAL HEPATITIS, UNSPECIFIED
B180	CHRONIC VIRAL HEPATITIS B WITH DELTA-AGENT
B181	CHRONIC VIRAL HEPATITIS B WITHOUT DELTA-AGENT
B182	CHRONIC VIRAL HEPATITIS C
B188	OTHER CHRONIC VIRAL HEPATITIS
B189	CHRONIC VIRAL HEPATITIS, UNSPECIFIED
B190	UNSPECIFIFED VIRAL HEPATITIS WITH HEPATIC COMA
B1910	UNSPECIFIED VIRAL HEPATITIS B WITHOUT HEPATIC COMA
B1911	UNSPECIFIED VIRAL HEPATITIS B WITH HEPATIC COMA
B1920	UNSPECIFIED VIRAL HEPATITIS C WITHOUT HEPATIC COMA
B1921	UNSPECIFIED VIRAL HEPATITIS C WITH HEPATIC COMA
B199	UNSPECIFIED VIRAL HEPATITIS WITHOUT HEPATIC COMA

Step 4 (diagnosis of hepatic disease or hepatic impairment) **Required diagnosis:** *1* **Look back timeframe:** *365 days*	
ICD-10 Code	**Description**
K700	ALCOHOLIC FATTY LIVER
K7010	ALCOHOLIC HEPATITIS WITHOUT ASCITES
K7011	ALCOHOLIC HEPATITIS WITH ASCITES
K702	ALCOHOLIC FIBROSIS AND SCLEROSIS OF LIVER
K7030	ALCOHOLIC CIRRHOSIS OF LIVER WITHOUT ASCITES
K7031	ALCOHOLIC CIRRHOSIS OF LIVER WITH ASCITES
K7040	ALCOHOLIC HEPATIC FAILURE WITHOUT COMA
K7041	ALCOHOLIC HEPATIC FAILURE WITH COMA
K709	ALCOHOLIC LIVER DISEASE, UNSPECIFIED
K710	TOXIC LIVER DISEASE WITH CHOLESTASIS
K7110	TOXIC LIVER DISEASE WITH HEPATIC NECROSIS WITHOUT COMA
K7111	TOXIC LIVER DISEASE WITH HEPATIC NECROSIS WITH COMA
K712	TOXIC LIVER DISEASE WITH ACUTE HEPATITIS
K713	TOXIC LIVER DISEASE WITH CHRONIC PERSISTENT HEPATITIS
K714	TOXIC LIVER DISEASE WITH CHRONIC LOBULAR HEPATITIS
K7150	TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITHOUT ASCITES
K7151	TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITH ASCITES
K716	TOXIC LIVER DISEASE WITH HEPATITIS, NOT ELSEWHERE CLASSIFIED
K717	TOXIC LIVER DISEASE WITH FIBROSIS AND CIRRHOSIS OF LIVER
K718	TOXIC LIVER DISEASE WITH OTHER DISORDERS OF LIVER
K719	TOXIC LIVER DISEASE, UNSPECIFIED
K7200	ACUTE AND SUBACUTE HEPATIC FAILURE WITHOUT COMA
K7201	ACUTE AND SUBACUTE HEPATIC FAILURE WITH COMA
K7210	CHRONIC HEPATIC FAILURE WITHOUT COMA
K7211	CHRONIC HEPATIC FAILURE WITH COMA
K7290	HEPATIC FAILURE, UNSPECIFIED WITHOUT COMA
K7291	HEPATIC FAILURE, UNSPECIFIED WITH COMA
K730	CHRONIC PERSISTENT HEPATITIS, NOT ELSEWHERE CLASSIFIED
K731	CHRONIC LOBULAR HEPATITIS, NOT ELSEWHERE CLASSIFIED
K732	CHRONIC ACTIVE HEPATITIS, NOT ELSEWHERE CLASSIFIED
K738	OTHER CHRONIC HEPATITIS, NOT ELSEWHERE CLASSIFIED
K739	CHRONIC HEPATITIS, UNSPECIFIED
K740	HEPATIC FIBROSIS
K741	HEPATIC SCLEROSIS
K742	HEPATIC FIBROSIS WITH HEPATIC SCLEROSIS

Step 4 (diagnosis of hepatic disease or hepatic impairment) **Required diagnosis:** *1* **Look back timeframe:** *365 days*	
ICD-10 Code	**Description**
K743	PRIMARY BILIARY CIRRHOSIS
K744	SECONDARY BILIARY CIRRHOSIS
K745	BILIARY CIRRHOSIS, UNSPECIFIED
K7460	UNSPECIFIED CIRRHOSIS OF LIVER
K7469	OTHER CIRRHOSIS OF LIVER
K750	ABSCESS OF LIVER
K751	PHLEBITIS OF PORTAL VEIN
K752	NONSPECIFIC REACTIVE HEPATITIS
K753	GRANULOMATOUS HEPATITIS, NOT ELSEWHERE CLASSIFIED
K754	AUTOIMMUNE HEPATITIS
K7581	NONALCOHOLIC STEATOHEPATITIS (NASH)
K7589	OTHER SPECIFIED INFLAMMATORY LIVER DISEASES
K759	INFLAMMATORY LIVER DISEASE, UNSPECIFIED
K761	CHRONIC PASSIVE CONGESTION OF LIVER
K763	INFARCTION OF LIVER
K7689	OTHER SPECIFIED DISEASES OF LIVER
K769	LIVER DISEASE, UNSPECIFIED
K77	LIVER DISORDERS IN DISEASES CLASSIFIED ELSEWHERE

Evrysdi (Risdiplam)

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, Inc.; 2021. Available at **www.clinicalpharmacology.com**. Accessed on January 22, 2021.

3. Micromedex [online database]. Available at **www.micromedexsolutions.com**. Accessed on January 22, 2021.

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
01/22/2021	• Initial publication and presentation to the DUR Board