

**Texas Prior Authorization Program
Clinical Criteria**

Revised Jan. 15, 2021

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 |



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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 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 (\leq) 5mg per day?
 Yes (Approve – 365 days)
 No (Deny)

Renewal Requests (Manual Review):

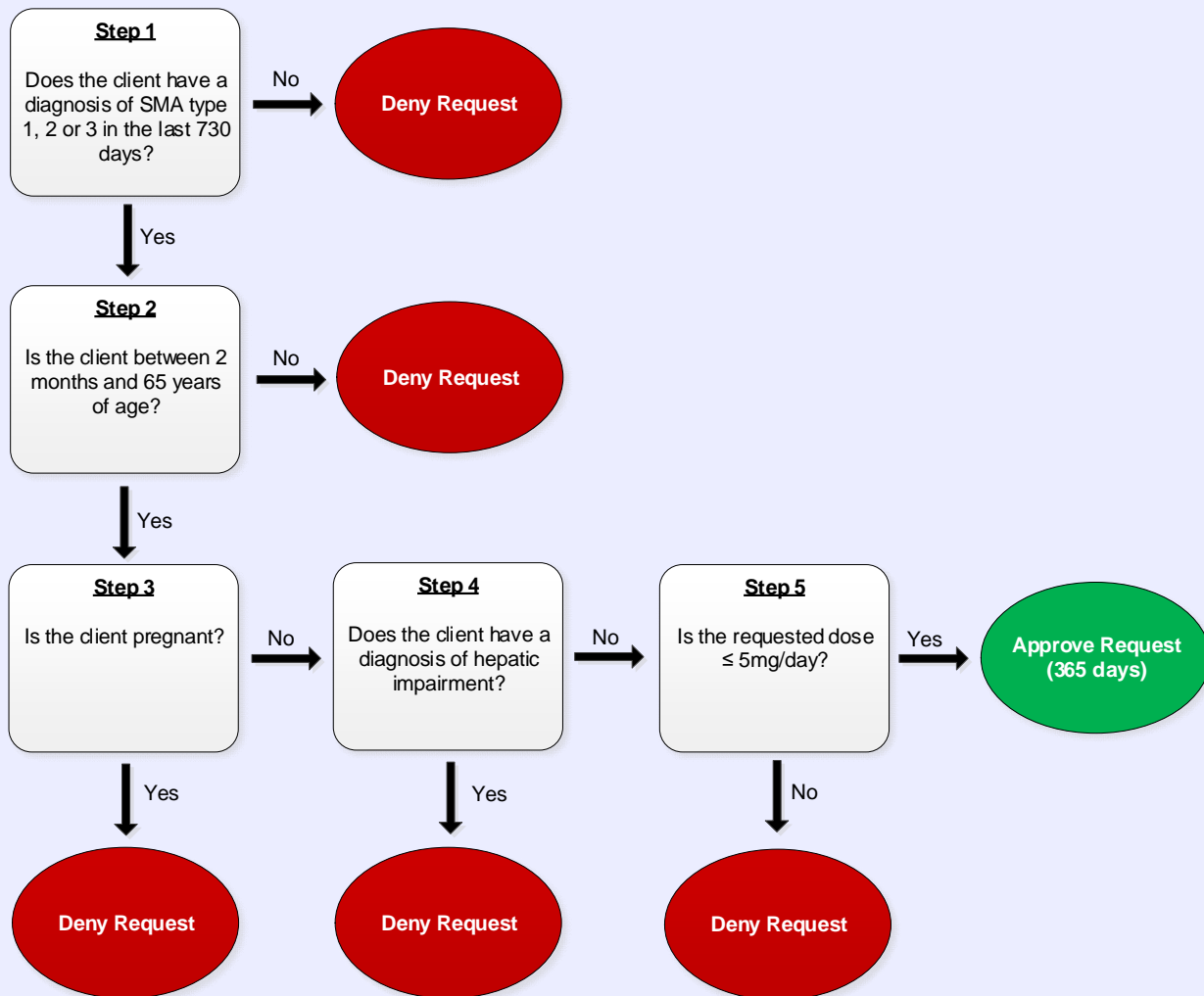
1. Is the client greater than ($>$) 65 years of age?
 Yes (Deny)
 No (And the client is female $<$ 51 years of age, go to #2)
 No (And the client is male or female \geq 51 years of age, go to #3)
2. Is the client **pregnant**?
 Yes (Deny)
 No (Go to #3)
3. Has the client had a positive response to treatment,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



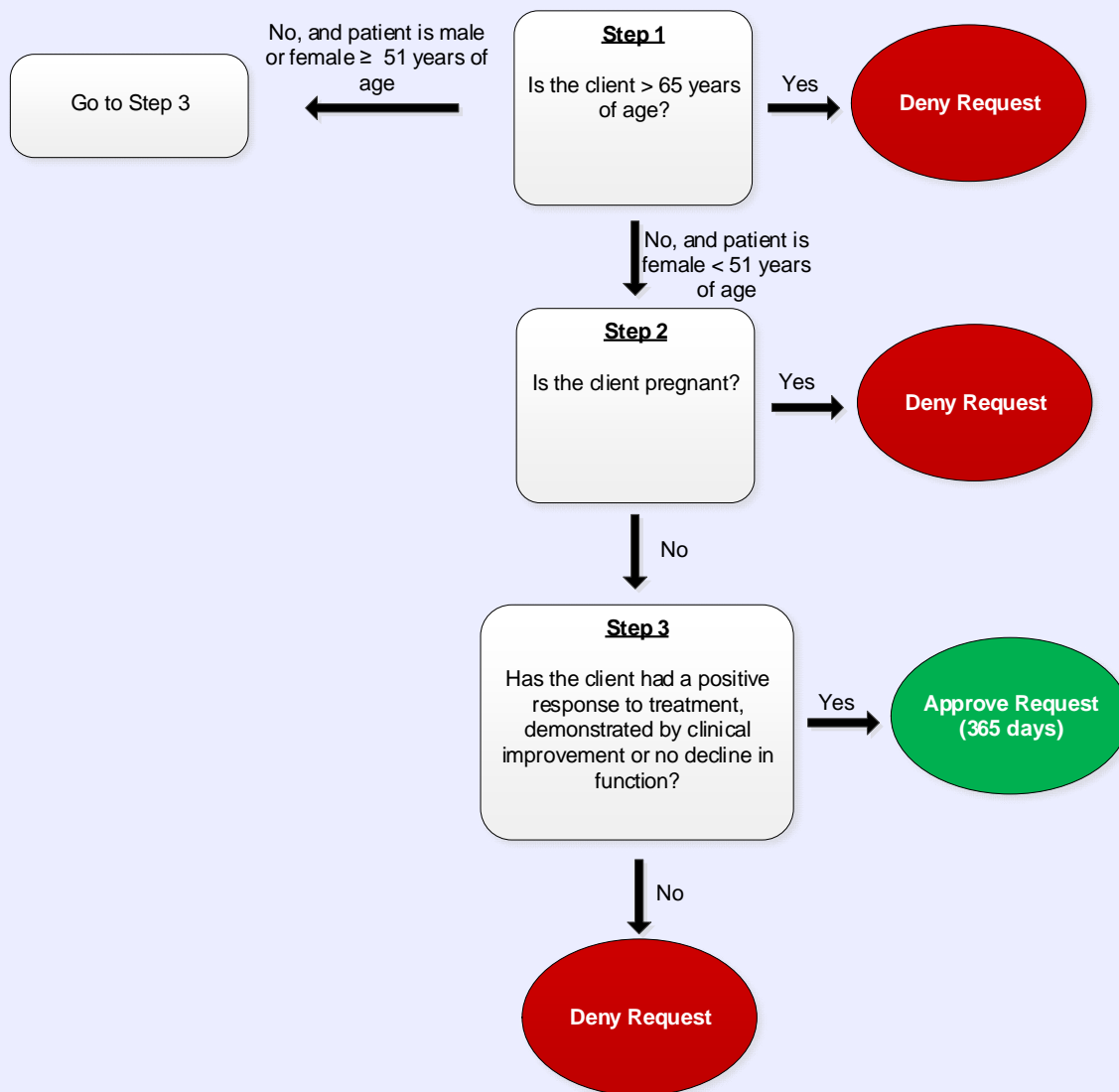
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Clinical Criteria Logic Diagram

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 |

| 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 | UNSPECIFIED 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 | <ul style="list-style-type: none">• Initial publication and presentation to the DUR Board |