Texas Prior Authorization Program
Clinical Criteria

Amyotrophic Lateral Sclerosis (ALS) Agents

Clinical Criteria Information Included in this Document

Relyvrio (Sodium phenylbutyrate/Taurusodiol)

- **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)
- **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 for the DUR Board

Relyvrio (Sodium phenylbutyrate/ Taurursodiol)

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**
RELYVRIO 3 GM-1 GM POWDER PKT	52696

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Clinical Criteria Logic

1. Does the client have a diagnosis of **amyotrophic lateral sclerosis (ALS)** in the last 730 days?
   [ ] Yes – Go to #2
   [ ] No – Deny

2. Is the client less than (<) 18 years of age?
   [ ] Yes – Deny
   [ ] No – Go to #3

3. Does the client have a **tracheostomy or permanent assisted ventilation**?
   [ ] Yes – Deny
   [ ] No – Go to #4

4. Does the client have 30 consecutive days of therapy with a **contraindicated drug** in the last 60 days, or will the client have concurrent use with a contraindicated drug?
   [ ] Yes – Deny
   [ ] No – Go to #5

5. Does the client have a diagnosis of **moderate to severe renal impairment or moderate to severe hepatic impairment** in the last 365 days?
   [ ] Yes – Deny
   [ ] No – Go to #6

6. Is the requested quantity less than or equal to (≤) to 2 packets daily?
   [ ] Yes – Approve (365 days)
   [ ] No – Deny

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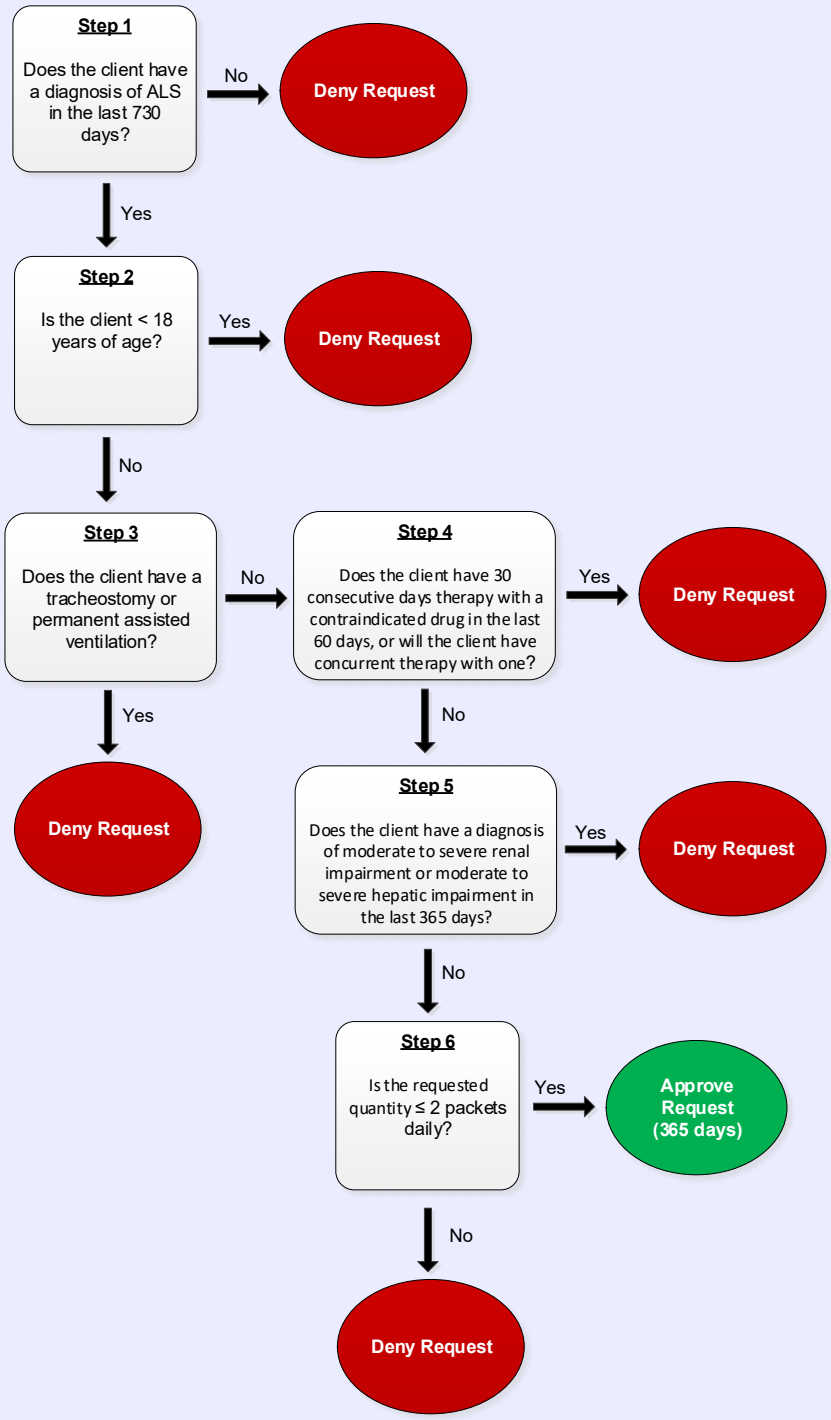
Clinical Criteria Logic Diagram



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Clinical Criteria Supporting Tables

Step 1 (diagnosis of ALS) **Required quantity:** *1* **Look back timeframe:** *730 days*	
ICD-10 Code	**Description**
G1221	AMYOTROPHIC LATERAL SCLEROSIS

Step 3 (tracheostomy or permanent assisted ventilation)	
ICD-10 Code	**Description**
Z930	TRACHEOSTOMY STATUS
Z9911	DEPENDENCE ON RESPIRATOR [VENTILATOR] STATUS

Step 4 (contraindicated drug) **Required quantity:** *1* **Look back timeframe:** *60 days*	
Label Name	**GCN**
CHOLESTYRAMINE LIGHT PACKET	09850
CHOLESTYRAMINE LIGHT POWDER	98654
CHOLESTYRAMINE PACKET	09920
CHOLESTYRAMINE POWDER	14295
COLESEVELAM 625 MG TABLET	16300
COLESEVELAM HCL 3.75 G PACKET	28064
COLESTID 1 GM TABLET	25442
COLESTID FLAVORED GRANULES	25441
COLESTID GRANULES	25450
COLESTID GRANULES PACKET	25440
COLESTIPOL HCL 1 GM TABLET	25442
COLESTIPOL HCL GRANULES	25450
COLESTIPOL HCL GRANULES PACKET	25440
CYCLOSPORINE 100 MG CAPSULE	13910
CYCLOSPORINE 25 MG CAPSULE	13911
CYCLOSPORINE MOD 100 MG	13919
CYCLOSPORINE MOD 100 MG/ML	13917
CYCLOSPORINE MOD 25 MG	13918
CYCLOSPORINE MOD 50 MG	13916

Step 4 (contraindicated drug) **Required quantity:** *1* **Look back timeframe:** *60 days*	
Label Name	**GCN**
DEPAKOTE DR 125 MG SPRINKLE CP	17400
DEPAKOTE DR 125 MG TABLET	17292
DEPAKOTE DR 250 MG TABLET	17290
DEPAKOTE DR 500 MG TABLET	17291
DEPAKOTE ER 250 MG TABLET	18754
DEPAKOTE ER 500 MG TABLET	18040
DIGOXIN 0.05 MG/ML SOLUTION	00120
DIGOXIN 125 MCG TABLET	00132
DIGOXIN 250 MCG TABLET	00133
DIGOXIN 62.5 MCG TABLET	00130
DIVALPROEX DR 125 MG CAP SPRNK	17400
DIVALPROEX SOD DR 125 MG TAB	17292
DIVALPROEX SOD DR 250 MG TAB	17290
DIVALPROEX SOD DR 500 MG TAB	17291
DIVALPROEX SOD ER 250 MG TAB	18754
DIVALPROEX SOD ER 500 MG TAB	18040
GENGRAF 100 MG CAPSULE	13919
GENGRAF 100 MG/ML SOLUTION	13917
GENGRAF 25 MG CAPSULE	13918
NEORAL 100 MG GELATIN CAPSULE	13919
NEORAL 100 MG/ML SOLUTION	13917
NEORAL 25 MG GELATIN CAPSULE	13918
NUEDEXTA 20-10 MG CAPSULE	29290
PREVALITE PACKET	09850
PREVALITE POWDER	98654
PROBENECID 500 MG TABLET	35072
PROBENECID-COLCHICINE TABLET	14029
QUESTRAN LIGHT POWDER	98654
QUESTRAN PACKET	09920
QUESTRAN POWDER	14295
QUINIDINE GLUC ER 324 MG TAB	01011
QUINIDINE SULFATE 200 MG TAB	01053
QUINIDINE SULFATE 300 MG TAB	01055
SANDIMMUNE 100 MG CAPSULE	13910
SANDIMMUNE 100 MG/ML SOLN	08220
SANDIMMUNE 25 MG CAPSULE	13911
VALPROIC ACID 250 MG CAPSULE	17270
VALPROIC ACID 250 MG/5 ML SOLN	17280

Step 4 (contraindicated drug) **Required quantity:** *1* **Look back timeframe:** *60 days*	
Label Name	**GCN**
WELCHOL 3.75 G PACKET	28064
WELCHOL 625 MG TABLET	16300

Step 5 (Diagnosis of moderate to severe renal impairment or moderate to severe hepatic impairment) **Required quantity:** *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
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

Step 5 (Diagnosis of moderate to severe renal impairment or moderate to severe hepatic impairment) **Required quantity:** *1* **Look back timeframe:** *365 days*	
ICD-10 Code	**Description**
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
K743	PRIMARY BILIARY CIRRHOSIS
K744	SECONDARY BILIARY CIRRHOSIS
K745	BILIARY CIRRHOSIS, UNSPECIFIED
K7460	UNSPECIFIED CIRRHOSIS OF LIVER

Step 5 (Diagnosis of moderate to severe renal impairment or moderate to severe hepatic impairment) **Required quantity:** *1* **Look back timeframe:** *365 days*	
ICD-10 Code	**Description**
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
N1830	CHRONIC KIDNEY DISEASE, STAGE 3 UNSPECIFIED (eGFR 59-30 mL/min)
N1831	CHRONIC KIDNEY DISEASE, STAGE 3A (eGFR 59-45 mL/min)
N1832	CHRONIC KIDNEY DISEASE, STAGE 3B (eGFR 44-30 mL/min)
N184	CHRONIC KIDNEY DISEASE, STAGE 4 (SEVERE) (eGFR 29-15 mL/min)
N185	CHRONIC KIDNEY DISEASE, STAGE 5 (eGFR < 15 mL/min)
N186	END STAGE RENAL DISEASE

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Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2023. Available at **www.clinicalpharmacology.com**. Accessed on July 21, 2023.

2. 2023 ICD-10-CM Diagnosis Codes, Volume 1. 2023. Available at **www.icd10data.com**. Accessed on July 21, 2023.

3. Relyvrio Prescribing Information. Cambridge, MA. Amylyx Pharmaceuticals, Inc. September 2022.

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Publication History

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
07/07/2023	Incorporated MCO suggestions for presentation
07/21/2023	Initial publication and presentation to the DUR Board