Texas Prior Authorization Program
Clinical Criteria

Drug/Drug Class

Transthyretin Agents

This criteria was recommended for review by an MCO to ensure appropriate and safe utilization

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

Transthyretin Agents

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**
VYNDAMAX 61 MG CAPSULE	46258
VYNDAQEL 20 MG CAPSULE	37584

RxPERT® PAxpress™

Transthyretin Agents

Clinical Criteria Logic

1. Is the medication being prescribed by, or in consultation with, a cardiologist or a prescriber that specializes in the treatment of transthyretin-mediated amyloidosis? [Manual]
   [ ] Yes (Go to #2)
   [ ] No (Deny)

2. Is the client greater than or equal to (≥) 18 years of age?
   [ ] Yes (Go to #3)
   [ ] No (Deny)

3. Does the client have a **diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM)** in the last 730 days?
   [ ] Yes (Go to #4)
   [ ] No (Deny)

4. Does the cardiac/non-cardiac tissue biopsy confirm the presence of amyloid deposits? [Manual]
   [ ] Yes (Go to #5)
   [ ] No (Deny)

5. Has the diagnosis been documented by confirmation of TTR precursor protein (wild type ATTR-CM) or confirmation of a TTR gene mutation (hereditary ATTR-CM)? [Manual]
   [ ] Yes (Go to #6)
   [ ] No (Deny)

6. Does the client have a diagnosis of New York Heart Association (NYHA) Functional Class (FC) IV heart failure? [Manual]
   [ ] Yes (Deny)
   [ ] No (Go to #7)

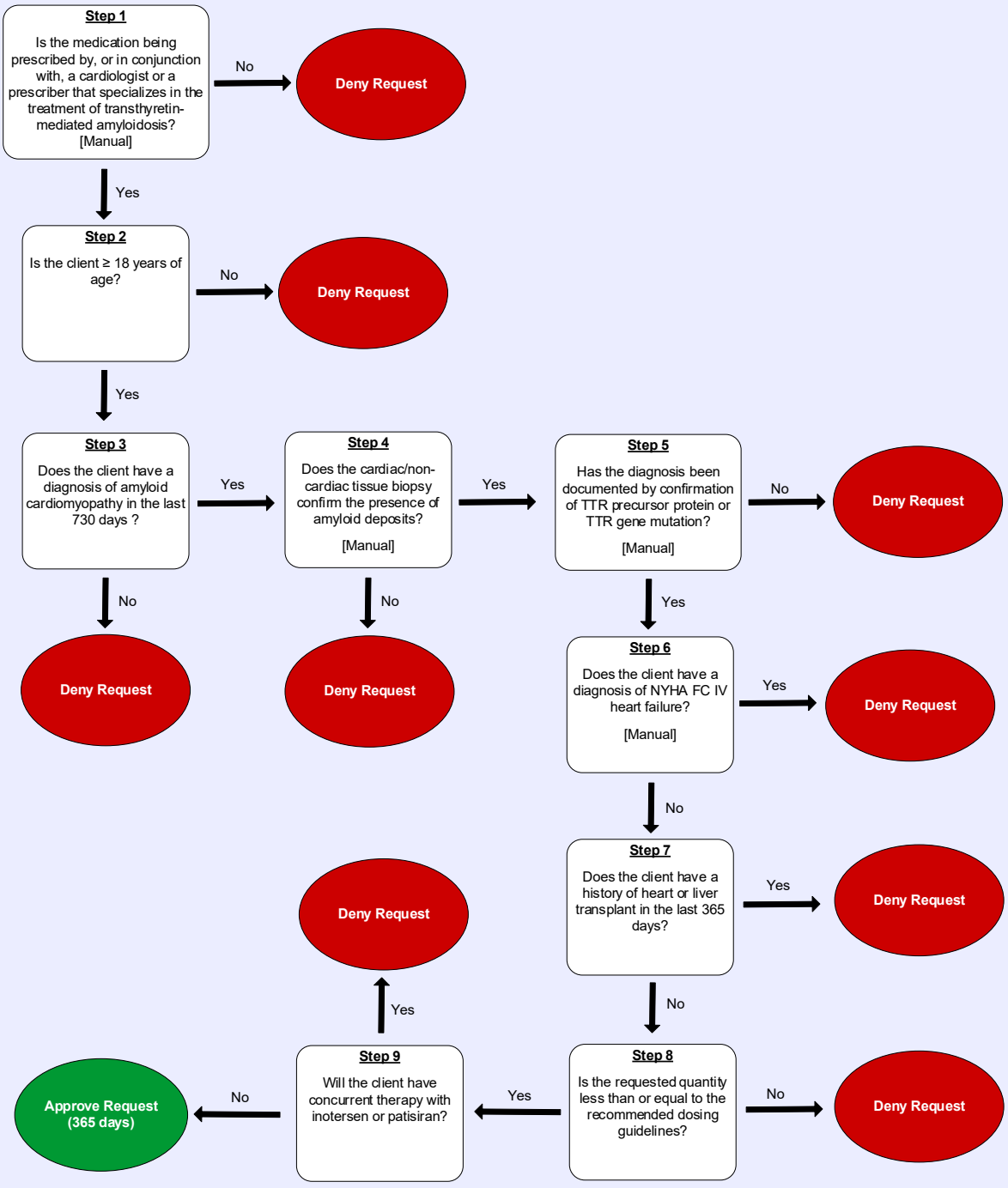
7. Does the client have a history of **heart or liver transplant** in the last 365 days?
   [ ] Yes (Deny)
   [ ] No (Go to #8)

8. Is the requested quantity less than or equal to the **recommended dosing guidelines**?
   [ ] Yes (Go to #9)
   [ ] No (Deny)

9. Will the client have **concurrent therapy with inotersen or patisiran**?
   [ ] Yes (Deny)
   [ ] No (Approve – 365 days)

Transthyretin Agents

Clinical Criteria Logic Diagram



RxPERT PAxpress

Transthyretin Agents

Clinical Criteria Supporting Tables

Step 3 (diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis) Required diagnosis: *1* Look back timeframe: *730 days*	
ICD-10 Code	**Description**
E854	ORGAN-LIMITED AMYLOIDOSIS
E8582	WILD-TYPE TRANSTHYRETIN-RELATED (ATTR) AMYLOIDOSIS

Step 7 (diagnosis of heart or liver transplant) Required diagnosis: *1* Look back timeframe: *365 days*	
ICD-10 Code	**Description**
Z941	HEART TRANSPLANT STATUS
Z944	LIVER TRANSPLANT STATUS

Step 8 Dosing Guidelines	
Label Name	**Recommended Dose**
Vyndamax 61 mg capsule	1 capsule daily
Vyndaqel 20 mg capsule	4 capsules once daily

Step 9 (inotersen/patisiran) Required claims: *1* Look back timeframe: *concurrent therapy*	
GCN	**Label Name**
45125	ONPATTRO 10MG/5ML VIAL
03721	TEGSEDI 284MG/1.5ML SYRINGE – PACK 1
03721	TEGSEDI 284MG/1.5ML SYRINGE – PACK 4

Transthyretin Agents

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**
TEGSEDI 284MG/1.5ML SYRINGE – PACK 1	03721
TEGSEDI 284MG/1.5ML SYRINGE – PACK 4	03721

RxPERT® PAXPRESS™

Transthyretin Agents

Clinical Criteria Logic

1. Is the medication being prescribed by, or in consultation with, a neurologist or provider that specializes in the treatment of transthyretin-mediated amyloidosis? [Manual]
   [ ] Yes (Go to #2)
   [ ] No (Deny)

2. Is the client greater than or equal to (≥) 18 years of age?
   [ ] Yes (Go to #3)
   [ ] No (Deny)

3. Does the client have a **diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis** in the last 730 days?
   [ ] Yes (Go to #4)
   [ ] No (Deny)

4. Is the client's platelet count greater than or equal to (≥) 100 X 10^9/L? [Manual]
   [ ] Yes (Go to #5)
   [ ] No (Deny)

5. Is the client's urine protein to creatinine ration (UPCR) less than (<) 1000mg/g? [Manual]
   [ ] Yes (Go to #6)
   [ ] No (Deny)

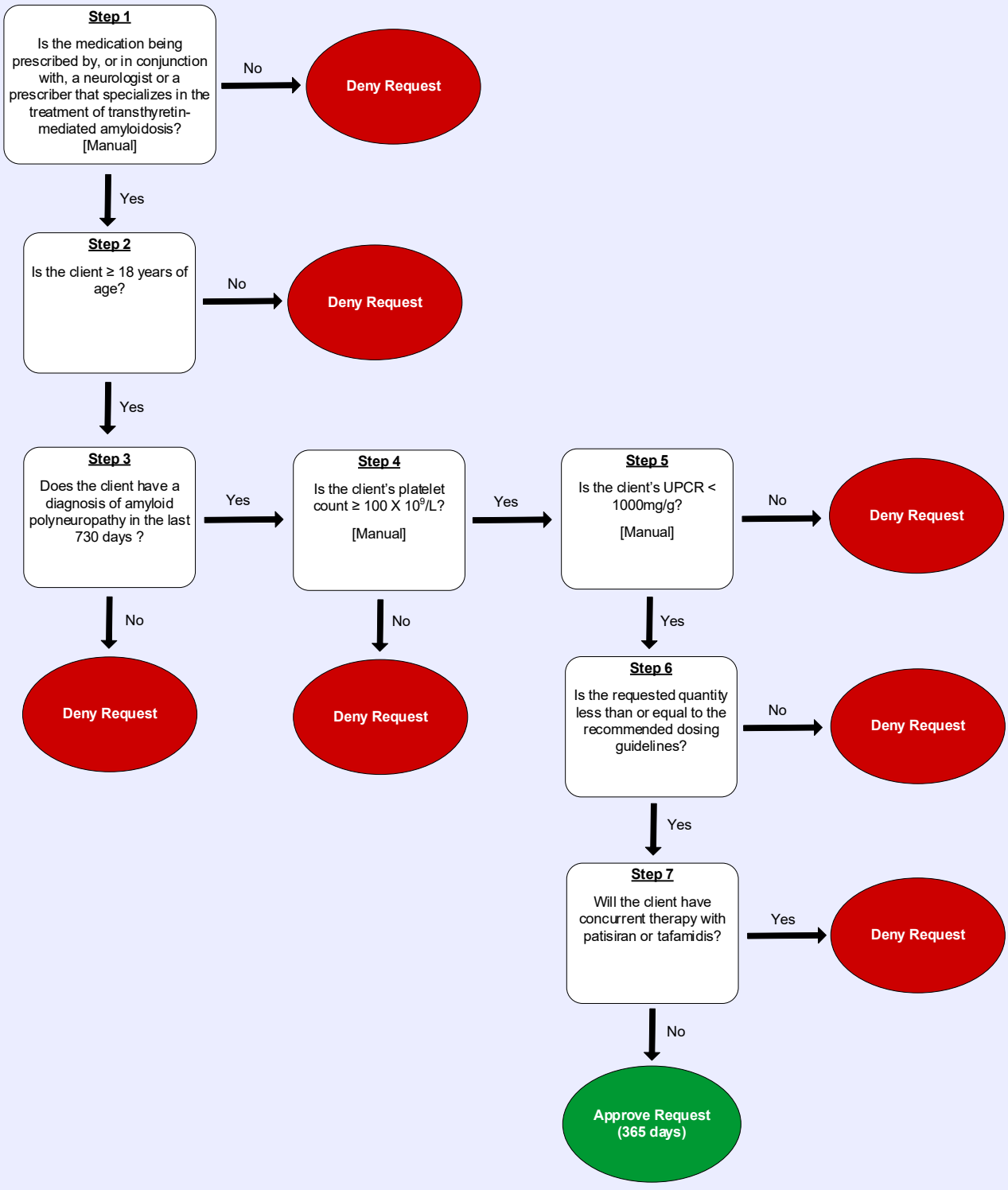
6. Is the requested quantity less than or equal to the **recommended dosing guidelines**?
   [ ] Yes (Go to #7)
   [ ] No (Deny)

7. Will the client have **concurrent therapy with patisiran or tafamidis**?
   [ ] Yes (Deny)
   [ ] No (Approve – 365 days)

RxPERT PAxpress™

Transthyretin Agents

Clinical Criteria Logic Diagram



RxPERT PAxpress

Transthyretin Agents

Clinical Criteria Supporting Tables

Step 3 (diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis) **Required diagnosis:** *1* **Look back timeframe:** *730 days*	
ICD-10 Code	**Description**
E851	NEUROPATHIC HEREDOFAMILIAL AMYLOIDOSIS

Step 6 Dosing Guidelines	
Label Name	**Recommended Dose**
Tegsedi 284mg/1.5mL syringe	284mg (1 syringe) SQ weekly

Step 7 (patisiran/tafamidis) **Required claims:** *1* **Look back timeframe:** *concurrent therapy*	
GCN	**Label Name**
45125	ONPATTRO 10MG/5ML VIAL
46258	VYNDAMAX 61 MG CAPSULE
37584	VYNDAQEL 20 MG CAPSULE

RxPERT® PAXPRESS™

Transthyretin Agents

Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2020. Available at **www.clinicalpharmacology.com**. Accessed on April 24, 2020.

2. Micromedex [online database]. Available at **www.micromedexsolutions.com**. Accessed on April 24, 2020.

3. Tegsedi Prescribing Information. Boston, MA. Akcea Therapeutics, Inc. October 2019.

4. Vyndamax/Vyndaqel Prescribing Information. New York, New York. Pfizer, Inc. August 2018.

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
04/24/2020	• Initial publication and presentation to the DUR Board