Drugs for Transthyretin-Mediated Amyloidosis (ATTR)

Goal(s):

- To limit utilization of medications for transthyretin mediated amyloidosis (ATTR) to FDA-approved indications and in populations with proven safety.

Length of Authorization:

- Up to 6 months

Requires PA: (Both pharmacy and physician-administered claims)

- All medications indicated for ATTR

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Table 1: FDA approved therapies for ATTR amyloidosis

Drug	Indication
Inotersen	Polyneuropathy of hereditary ATTR
Patisiran	Polyneuropathy of hereditary ATTR
Tafamidis	Cardiomyopathy of ATTR (hereditary and wild type)

Approval Criteria		
1. Is this a request for continuation of therapy previously approved by the FFS program?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #2
2. What diagnosis is being treated?	Record ICD10 code.	
3. Is this an FDA approved indication of ATTR amyloidosis supported by transthyretin mutation proven by genetic testing (See Table 1)?	**Yes**: Go to #4 Document Genotype: _____	**No:** Pass to RPh. Deny; medical appropriateness
4. Does the patient have clinical signs and symptoms of disease (peripheral/autonomic neuropathy, motor disability, cardiovascular dysfunction)?	**Yes**: Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. Is the request for or is the patient on concurrent use of more than one ATTR therapy (including diflunisal)?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #6
6. Has the patient had a liver transplantation?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #7
7. Is the request for patisiran or inoteren?	**Yes:** Go to #8	**No:** Go to #15

Approval Criteria		
8. Is baseline disease severity documented (polyneuropathy disability (PND) score and Familial amyloid polyneuropathy (FAP) stage)?	**Yes:** Document and Go to #9	**No:** Pass to RPh. Deny; medical appropriateness.
9. Was the medication prescribed or in consultation with a neurologist?	**Yes:** Go to #10	**No:** Pass to RPh. Deny; medical appropriateness.
10. Is the patient on Vitamin A supplementation or have a documented normal level?	**Yes:** Go to #11	**No:** Pass to RPh. Deny; medical appropriateness.
11. Is the request for patisiran?	**Yes**: Approve for 6 months	**No**: Go #12
12. Is the request for inotersen?	**Yes:** Go to #13	**No:** Go to #15
13. Has a baseline platelet count been obtained in the previous 3 months and are platelets ≥ 125 X 10^9/L?	**Yes:** Go to #14 Document baseline platelet count:_____ Date of Lab:_____	**No:** Pass to RPh. Deny; medical appropriateness.
14. Has baseline renal function been evaluated in the previous 3 months?	**Yes:** Approve for 6 months Document baseline serum creatinine and BUN:_____ Date of Lab:_____	**No:** Pass to RPh. Deny; medical appropriateness
15. Is the request for tafamidis?	**Yes:** Go to #16	**No:** Go to #18
16. Was the medication prescribed or in consultation with a cardiologist?	**Yes:** Go to #17	**No:** Pass to RPh. Deny; medical appropriateness.
17. Does the patient have a medical history of heart failure (NYHA class I-III) with at least one prior hospitalization for heart failure?	**Yes:** Approve for 6 months	**No:** Pass to RPh. Deny; medical appropriateness
18. Is the request for a newly approved hATTR therapy and does the indication match the FDA approved indication?	**Yes:** Approve for 6 months	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Has the patient had a documented response to treatment including at least one of the following: a. Improved neurologic impairment b. Improved motor function c. Improved quality of life d. Improved cardiac function	**Yes:** Go to #2	**No:** Pass to RPh; Deny (medical appropriateness)
2. Is the prescribed medication tafamidis?	**Yes:** Approve for 12 months	**No:** Go to #3
3. Has the patient experienced stabilization OR improvement from baseline in one of the following: a. Baseline polyneuropathy disability (PND) score b. Familial amyloid polyneuropathy (FAP) stage	**Yes:** Go to #4	**No:** Pass to RPh; Deny (medical appropriateness)
4. Is the renewal for inotersen?	**Yes:** Go to #5	**No:** Approve for 12 months
5. Does the patient have a platelet count ≥ 100 X 10^9/L?	**Yes:** Approve for 12 months	**No:** Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: 9/19; 7/19 (MH)
Implementation: 11/1/19