Prior Authorization Request Form for **inotersen injection (Tegsedi)**

JOHNS HOPKINS MEDICINE
JOHNS HOPKINS HEALTHCARE
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FAX Completed Form and Applicable Progress Notes to: (410) 424-4037

USFHP Pharmacy Prior Authorization Form

To be completed by Requesting provider	
Drug Name:	Strength:
Dosage/Frequency (SIG):	Duration of Therapy:

Questions? Contact the Pharmacy Dept at: (888) 819-1043, option 4

Clinical Documentation must accompany form in order for a determination to be made.

Step 1 **Please complete patient and physician information** (please print):

Patient Name: _____ Physician Name: _____
Address: _____ Address: _____
_____ _____
Sponsor ID # _____ Phone #: _____
Date of Birth: Secure Fax #:

Step 2 **Please complete the clinical assessment:**

1. Will the requested medication be used in combination with Onpattro?	☐ Yes **STOP** Coverage not approved	☐ No Proceed to question **2**
2. Is this medication being prescribed by or in consultation with a specialist that manages hereditary transthyretin amyloidosis (such as cardiologist, geneticist, or neurologist)?	☐ Yes Proceed to question **3**	☐ No **STOP** Coverage not approved
3. Is the patient 18 years of age or older?	☐ Yes Proceed to question **4**	☐ No **STOP** Coverage not approved
4. Does the patient have a genetically confirmed transthyretin mutation resulting in familial amyloidotic polyneuropathy (FAP) stage 1 or 2 hereditary transthyretin-mediatedamyloidosis (hTTRA)?	☐ Yes Proceed to question **5**	☐ No **STOP** Coverage not approved
5. Does the patient have polyneuropathy secondary to hereditary transthyretin-mediated amyloidosis?	☐ Yes Proceed to question **6**	☐ No **STOP** Coverage not approved
6. Does the patient have a polyneuropathy disability (PND) score less than or equal to IIIB or 2?	☐ Yes Proceed to question **8**	☐ No Proceed to question **7**
7. Does the patient have a Neuropathy Impairment Score between 10 and 130?	☐ Yes Proceed to question **8**	☐ No **STOP** Coverage not approved

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8. Are both the provider and patient registered and enrolled with the Tegsedi Risk Evaluation and Mitigation Strategies (REMS) program?	☐ Yes Proceed to question **9**	☐ No **STOP** Coverage not approved
9. Is there evidence of thrombocytopenia in the patient?	☐ Yes **STOP** Coverage not approved	☐ No Proceed to question **10**
10. Does the patient have chronic kidney disease (CKD) stage 3b?	☐ Yes **STOP** Coverage not approved	☐ No Proceed to question **11**
11. Does the patient have a history of glomerulonephritis?	☐ Yes **STOP** Coverage not approved	☐ No Proceed to question **12**
12. Will the provider monitor the patient's platelet counts and renal and hepatic function while receiving the requested medication?	☐ Yes Proceed to question **13**	☐ No **STOP** Coverage not approved
13. Will the patient take an oral Vitamin A supplement at the recommended daily allowance while receiving the requested medication?	☐ Yes Proceed to question **14**	☐ No **STOP** Coverage not approved
14. Is the provider aware and is the patient informed of the following potential adverse drug reactions: stroke, encephalitis, carotid arterial dissection, hypercoagulability and thrombosis (venous and arterial), QRS prolongation and other arrhythmias, elevated liver-associated enzymes, autoimmune hepatitis, primary biliary cirrhosis, biliary obstruction, glomerulonephritis, nephrotic syndrome, interstitial nephritis, thrombocytopenia, idiopathic thrombocytopenia (ITP), antineutrophil cytoplasmic antibody-associated (ANCA) vasculitis, and hypersensitivity?	☐ Yes **Sign and date below**	☐ No **STOP** Coverage not approved

Step 3 **I certify the above is true to the best of my knowledge.** Please sign and date:

_____ _____

Prescriber Signature Date

[29 May 2019]

For Internal Use Only	
☐ Approved:	Duration of Approval: _____month(s)
☐ Denied:	Authorized By:
☐ Incomplete/Other:	PA#:
Date Faxed to MD:	Date Decision Rendered: