TEGSEDI® REMS
Patient Status Form

This form must be completed for all patients treated with TEGSEDI as follows:

- Every 90 days following the first dispense of TEGSEDI treatment
- At discontinuation of TEGSEDI treatment
- At 8 weeks following discontinuation of TEGSEDI treatment (*this is the final 8 week Patient Status Form*)
- **At any time there is a change in prescriber or transfer of care**

Submit the completed form:

- Online at www.TEGSEDIrems.com
- Or Fax: 1-855-4TEGREMS (855-483-4736)

NOTE: Laboratory monitoring is done more frequently than the submission of this form.

Laboratory Monitoring

Following treatment initiation, certified prescribers must assess each patient's platelet count and renal function [estimated glomerular filtration rate (eGFR), urinalysis, and urine protein to creatinine ratio (UPCR)] and appropriateness of continuing treatment as follows:

- Platelet count: Every week or more frequently as described in the Prescribing Information
- Renal function: Every 2 weeks

After a treatment discontinuation, the patient's platelet count and renal function must continue to be monitored for 8 weeks as follows:

- Platelet count: Every week or more frequently as described in the Prescribing Information
  Renal function: Every two weeks

PRESCRIBER INFORMATION (*required)		
National Provider Identifier #*:		
First Name*:	Last Name*:	
Practice/Facility Name:		
Address Line 1:		
Address Line 2:		
City:	State:	Zip Code:
Phone:	Fax:	Email:

PATIENT INFORMATION (PLEASE PRINT) (*required)		
First Name*:	Last Name*:	Birthdate* (MM/DD/YYYY):
Address Line 1*:		
Address Line 2:		
City*:	State*:	Zip Code*:

Tegsedi® (inotersen) injection 284 mg/1.5 mL

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PATIENT INFORMATION		
Last Name:	First Name:	Birthdate (MM/DD/YYYY):

1.	I have assessed the patient's signs and symptoms and reviewed the patient's required laboratory tests [platelet count, estimated glomerular filtration rate (eGFR), urinalysis, and urine protein to creatinine ratio (UPCR)] during this reporting period.	☐ YES ☐ NO
2.	Is it appropriate for the patient to continue to receive TEGSEDI? (Not applicable for the 8 week final Patient Status form)	☐ YES ☐ NO
2a.	If NO, please indicate the reason(s) the patient has discontinued therapy with TEGSEDI: ☐ Thrombocytopenia Please check one: ☐ < 25 ×10^9/L ☐ ≥ 25 to < 50 x10^9/L ☐ ≥ 50 to < 75 x10^9/L ☐ ≥ 75 to < 100 ×10^9/L ☐ Glomerulonephritis ☐ Death Date: _____ Cause: _____ ☐ Other _____ ***Please report all other Adverse Events to Akcea Therapeutics at 1-833-642-5232***	
3.	If patient discontinued due to severe thrombocytopenia (platelet count <50×10^9/L), did the patient experience serious bleeding?	☐ YES ☐ NO
3a.	If YES, did the patient have a platelet measurement within 2 weeks of the start of bleeding?	☐ YES ☐ NO
4.	Is the above-named patient still under the care of the prescriber identified above?	☐ YES ☐ NO
4a.	If NO, (not applicable if death is checked for 2a) HCP now responsible for this patient's care Name: _____ Phone Number: _____ ☐ HCP now responsible for this patient's care is unknown	

Please note: A delegate may submit this form on behalf of the TEGSEDI REMS-certified prescriber of record. The certified prescriber of record is responsible for compliance and the content of the form (i.e. evaluation) with the TEGSEDI REMS requirements, including monitoring, evaluation, and management of each patient under his/her care.

Submitted by*: ☐ Prescriber ☐ Prescriber Delegate

Print Name*:	
Signature*: X _____	Signature Date* (MM/DD/YYYY):

If you have questions about the REMS, you can call the TEGSEDI REMS Coordinating Center at 1-844-483-4736, 8:00 am-8:00 pm EST.

Phone: 1-844-483-4736 | www.TEGSEDIrems.com | Fax: 1-855-483-4736

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