TEGSEDI® REMS
Patient Enrollment Form

TEGSEDI is available only through the TEGSEDI REMS, a restricted distribution program. Only prescribers, pharmacies, and patients enrolled in the program can prescribe, dispense, and receive TEGSEDI. Your certified healthcare provider will help you complete this form and provide you with a copy.

Prescribers and patients: Please complete this form online at www.TEGSEDIrems.com or, once completed, fax it to the REMS at 1-855-483-4736.

**Indicates required field*

PATIENT INFORMATION				
First Name*:	Last Name*:	MI:	Gender: ☐ M ☐ F	Date of Birth (Month/Day/Year)*:
Email:				
Address Line 1*:				
Address Line 2:				
City*:	State*:	ZIP Code*:		Phone Number*:
Preferred method(s) of contact: ☐ Phone ☐ Email				

PRESCRIBER INFORMATION		
First Name*:	Last Name*:	
Practice/Facility Name:		
Address Line 1:		
Address Line 2:		
City:	State:	ZIP Code:
Email:		
Phone Number*:	DEA:	NPI*:

Healthcare provider: Provide a copy of this form to the patient.

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

Tegsedi® (inotersen) injection 284 mg/1.5 mL

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PRESCRIBER AGREEMENT

By signing below, I attest that prior to prescribing TEGSEDI:

- I have assessed the patient's platelet count, estimated glomerular filtration rate, urinalysis, and urine protein to creatinine ratio and determined that it is appropriate for this patient to receive TEGSEDI
- I have counseled my patient on how to recognize and respond to signs and symptoms of serious bleeding and glomerulonephritis and the need for mandatory ongoing platelet and renal function monitoring
- I have counseled my patient with the ***Patient Guide*** and the ***Wallet Card***

Prescriber Signature*: X _____	Date*:

PATIENT AGREEMENT

By signing below, I understand and I acknowledge that:

Before my treatment begins, I will:

- Review the ***Patient Guide*** and ***Wallet Card***
- Enroll in the REMS by completing the ***Patient Enrollment Form*** with my healthcare provider. Enrollment information will be provided to the REMS
- Get a blood test to check my platelet count and a blood test and urine test to check my kidneys
- Receive counseling from my healthcare provider on the risk of serious bleeding, the risk of kidney inflammation (glomerulonephritis) and kidney failure, and the need to complete the appropriate laboratory testing using the ***Patient Guide*** and ***Wallet Card***

During treatment every week or more frequently as directed by my healthcare provider, I will:

Get a blood test to check my platelet count

During treatment every two weeks, I will:

- Get a blood test and urine test to check my kidneys

If my healthcare provider has me stop taking TEGSEDI, I will:

- Continue to get my blood and urine tested every 1-2 weeks or more frequently as directed by my healthcare provider, for 8 more weeks

I understand that:

- I will contact my healthcare provider or go to the emergency room if I have any side effects, reactions, or symptoms after receiving TEGSEDI
- I have received, read, and understand that I will carry the ***Wallet Card*** with me at all times
- I have received, read, and understand the ***Patient Guide*** that my healthcare provider has given me
- TEGSEDI can cause serious side effects. It can cause low platelet counts that may lead to serious bleeding that could lead to death. It can also cause kidney inflammation and kidney failure that needs dialysis. These complications can be identified through lab testing and awareness of side effects, reactions, or symptoms. My healthcare provider has reviewed with me the risks of treatment with TEGSEDI
- In order to receive TEGSEDI, I am required to be enrolled in the REMS, and my information will be stored in a database of all patients who receive TEGSEDI in the United States
- Akcea Therapeutics and its agents, including trusted vendors, may contact me via phone, mail, fax, or email to support administration of the REMS
- Akcea Therapeutics and its agents, including trusted vendors, may use, disclose, and share my personal health information for the purpose of the operations of the REMS, including enrolling me into the REMS and administering the REMS, coordinating the dispensing of TEGSEDI, and releasing and disclosing my personal health information to the Food and Drug Administration (FDA), as necessary, and as otherwise required by law

**Indicates required field*

Printed Patient or Legal Guardian First and Last Name:	
Patient or Legal Guardian Signature*: X _____	Date*:

Healthcare provider: Provide a copy of this form to the patient.

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