TEGSEDI® REMS
Prescriber Knowledge Assessment

Prescriber Name:	Date:
Prescriber NPI:	
Prescriber Email:	Prescriber Phone:

To become a certified prescriber in the TEGSEDI REMS, you have 3 attempts to answer all questions correctly.

- Review the Prescribing Information, *Prescriber Training* and *Program Overview*.
- Complete this *Prescriber Knowledge Assessment* and the *Prescriber Enrollment Form* via TEGSEDIREMSCC.com

Or

- Fax your responses to the *Prescriber Knowledge Assessment* questions and the *Prescriber Enrollment Form* to 1-855-4TEGREMS (855-483-4736).
- You will be notified via email by the TEGSEDI REMS Program on the status of your certification within two business days of submitting. When contacted, you will receive either:

  – Confirmation of your certification in the TEGSEDI REMS Program

Or

  – Instructions on how to retake the *Prescriber Knowledge Assessment*. You will be given the opportunity to retake the test by providing answers for only the questions you answered incorrectly. If you do not answer all questions correctly in 3 attempts, you will be instructed to re-review the materials and once reviewed, you will have another 3 attempts to complete the test.

  – If the *Prescriber Knowledge Assessment* is not successfully completed after 6 attempts, you will be contacted by the TEGSEDI REMS via telephone and informed that a representative from Sobi, Inc., on behalf of Akcea Therapeutics will reach out to discuss your certification.

Tegsedi® (inotersen) injection 284 mg/1.5 mL

TEGSEDI® REMS

Prescriber Knowledge Assessment

Prescriber Last Name:	Prescriber First Name:

Questions 1-10

Question 1 (check one)

To certify in the TEGSEDI REMS Program I must:

- ☐ A. Review the Prescribing Information
- ☐ *B.* Review the *Prescriber Training*
- ☐ *C.* Successfully complete the *Prescriber Knowledge Assessment*
- ☐ *D.* Enroll in the TEGSEDI REMS by completing and signing the *Prescriber Enrollment Form*
- ☐ E. All of the above

Question 2 (check one)

TEGSEDI can cause severe thrombocytopenia that may occur suddenly

- ☐ True
- ☐ False

Question 3 (check one)

Before TEGSEDI treatment (first dose), I must:

- ☐ A. Counsel the patient on how to recognize and respond to signs and symptoms of serious bleeding and glomerulonephritis and the need to have their platelets and renal function monitored, using the *Patient Guide* and *Wallet Card*
- ☐ *B.* Provide the patient with the *Patient Guide* and *Wallet Card*
- ☐ C. Assess the patient's platelet count and appropriateness of initiating treatment
- ☐ D. Assess the patient's estimated glomerular filtration rate (eGFR), urinalysis, and urine protein to creatinine ratio (UPCR) and appropriateness of initiating treatment
- ☐ E. Enroll the patient by completing and submitting the *Patient Enrollment Form* to the REMS Program and provide a completed copy of the form to the patient
- ☐ F. All of the above

Question 4 (check one)

Testing and monitoring for severe thrombocytopenia, serious bleeding with severe thrombocytopenia, and glomerulonephritis is not a requirement of the TEGSEDI REMS

- ☐ True
- ☐ False

Question 5 (check one)

At all times during treatment with TEGSEDI a prescriber must:

Report events of severe thrombocytopenia, serious bleeding with severe thrombocytopenia, and glomerulonephritis to the REMS Program and report treatment discontinuation or transfer of care to the REMS Program

- ☐ True
- ☐ False

Question 6

Match each lab value to the monitoring frequency as described in the TEGSEDI Prescribing Information (PI) during treatment:

Platelets (check one)	☐ A.	☐ B.	☐ C.	☐ D.
eGFR (check one)	☐ A.	☐ B.	☐ C.	☐ D.
Urinalysis (check one)	☐ A.	☐ B.	☐ C.	☐ D.
UPCR (check one)	☐ A.	☐ B.	☐ C.	☐ D.

A. Do not need monitoring
B. Weekly or more frequently as described in the PI.
C. Every 2 weeks
D. Every 3 months

Question 7 (check one)

If a platelet measurement is uninterpretable, I should hold TEGSEDI dosing until an acceptable platelet count is confirmed with an interpretable blood sample

- ☐ True
- ☐ False

Question 8 (check one)

I should complete and submit a *Patient Status Form* to the REMS Program:

- ☐ A. At treatment discontinuation
- ☐ B. Every 90 days during treatment
- ☐ C. Eight weeks following discontinuation of TEGSEDI
- ☐ D. Every 2 months during treatment
- ☐ E. A, B & C above

Question 9 (check one)

TEGSEDI can cause glomerulonephritis

- ☐ True
- ☐ False

Question 10 (check one)

TEGSEDI should not generally be initiated in patients, or treatment continued to be given to patients who have or develop a urinary protein to creatinine ratio (UPCR) of _____ or higher.

- ☐ A. 1000 mg/g
- ☐ B. 500 mg/g
- ☐ C. 200 mg/g

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