Abecma (idecabtagene vicleucel) SUSPENSION FOR IV INFUSION

ABECMA® REMS Knowledge Assessment

All Risk Evaluation and Mitigation Strategy (REMS)–trained staff and authorized representatives (ARs) must complete this Knowledge Assessment. All questions must be answered correctly within 3 attempts. Completion of this Knowledge Assessment does not guarantee that your institution will be certified to administer ABECMA.

You can take the Knowledge Assessment online at www.AbecmaREMS.com or by completing a paper copy. All Knowledge Assessments taken via paper must be submitted to the AR, who must send them to Celgene Corporation, a Bristol-Myers Squibb Company, via email at REMSCallCenter@bms.com, or by fax to 1-855-496-8607.

Knowledge Assessment Personnel Information (all fields required):

I am the AR ☐ Yes ☐ No

First Name _____ Last Name _____

Job Title _____

Credentials

☐ MD ☐ DO ☐ PA ☐ RPh ☐ NP ☐ Other (please specify): _____

REMS Site ID: (if providing site ID, do not fill in address below)

Address _____

City _____ State _____ ZIP Code _____

Phone _____

Work Email Address _____

Signature _____ Date (MM/DD/YYYY) _____

To Be Completed by the Authorized Representative:

Please indicate which questions were answered correctly by writing yes (Y) or no (N) below.

Knowledge Assessment Attempt	Question												Total Grade (example: 7/12)
	1	2	3	4	5	6	7	8	9	10	11	12	
1													
2													
3													

All REMS-trained staff have 3 attempts to complete this Knowledge Assessment. After a third attempt, staff must repeat the REMS Training Program before taking the Knowledge Assessment again.

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ABECMA® REMS Knowledge Assessment Questions

1. What is the approved indication for ABECMA?

- ○ A. Relapsed or refractory (R/R) large B-cell lymphoma after ≥2 prior therapies
- ○ B. Adult patients with relapsed or refractory multiple myeloma after 4 or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody
- ○ C. Primary central nervous system myeloma
- ○ D. Newly diagnosed untreated multiple myeloma

2. Which of the following is true regarding the time to onset of cytokine release syndrome (CRS)?

- ○ A. Median time to onset is 1 day
- ○ B. Median time to onset is 5 days
- ○ C. Median time to onset is 2 days
- ○ D. Rarely starts during the first week following ABECMA infusion

3. All of the following regarding neurologic toxicity related to ABECMA are correct, except:

- ○ A. Neurologic toxicity always occurs concurrently with CRS
- ○ B. Perform neurologic work-up as appropriate to exclude other etiologies of neurologic symptoms
- ○ C. The median time to onset of neurologic toxicity is 2 days
- ○ D. The most common signs or symptoms of neurologic toxicity include encephalopathy, tremor, aphasia, and delirium

4. Every ABECMA REMS-certified institution is required to have a minimum of 2 doses of tocilizumab on site for each patient prior to dispensing and administering ABECMA:

- ○ True
- ○ False

5. Delay the infusion of ABECMA for up to 7 days if a patient has any of the following conditions:

- ○ A. Unresolved serious adverse events (especially pulmonary events, cardiac events, or hypotension) including those after preceding chemotherapies
- ○ B. Active infections or inflammatory disorders
- ○ C. None of these
- ○ D. A and B

6. A 75-year-old female treated with ABECMA 1 day ago develops a fever >38 °C, myalgias, and mild hypotension that responded to an IV fluid bolus. What is/are the appropriate next step(s) in management?

- ○ A. Evaluate the patient for febrile neutropenia/sepsis by obtaining blood and urine cultures, chest X-ray, and complete blood count, and start broad spectrum antibiotics
- ○ B. Administer a dose of tocilizumab
- ○ C. Discharge the patient home to follow up the next day in the outpatient oncology clinic
- ○ D. A and B

7. Before ABECMA infusion, patients should be given the ABECMA Patient Wallet Card and be advised to:

- ○ A. Refrain from driving or operating heavy or potentially dangerous machinery until at least 8 weeks following infusion
- ○ B. Remain close to the certified treating institution for at least 4 weeks following infusion
- ○ C. Seek immediate medical attention if they experience signs or symptoms of CRS and/or neurologic toxicities
- ○ D. All of the above

8. Clinically, ABECMA patients with CRS can manifest the following signs and symptoms, except:

- ○ A. Hypotension
- ○ B. A fever of 100.4 °F (38 °C) or higher
- ○ C. Hives
- ○ D. Chills or shaking chills

9. Two days after infusion of ABECMA, a 70-year-old female develops the following signs and symptoms of CRS: fever >38 °C, hypotension requiring intravenous fluids, and hypoxia requiring ≥40% FiO_2. This patient's CRS grade would be most consistent with:

- ○ A. Grade 1 CRS
- ○ B. Grade 2 CRS
- ○ C. Grade 3 CRS
- ○ D. Grade 4 CRS

10. A 65-year-old male treated with ABECMA 2 days ago has moderate confusion and difficulty speaking that began an hour ago. He did not have any preceding signs or symptoms of CRS since infusion. What is/are the appropriate next step(s) in management:

- ○ A. Obtain imaging of the head to evaluate for the possibility of stroke
- ○ B. Start tocilizumab 8 mg/kg intravenously over 1 hour (not to exceed 800 mg)
- ○ C. Start dexamethasone 10 mg intravenously every 12 to 24 hours
- ○ D. Start nonsedating antiseizure medicines (eg, levetiracetam) for seizure prophylaxis
- ○ E. All of the above except B

11. A 64-year old male developed grade 2 CRS 2 days after receiving ABECMA. Despite receiving tocilizumab and steroids for 48 hours, he has progression of symptoms with worsening hypotension, hypoxia, fever, cytopenia, and worsening renal function. What is/are the appropriate next step(s) in management:

- ○ A. Evaluate and treat for hemophagocytic lymphohistiocytosis/ macrophage activation syndrome (HLH/MAS)
- ○ B. Optimize management of CRS if HLH/MAS is ruled out
- ○ C. Optimize antibiotics, antiviral and antifungal therapy
- ○ D. All of the above

12. The following were observed in the KarMMa study:

- ○ A. Prolonged neutropenia in 41% and prolonged thrombocytopenia in 49% of the patients treated with ABECMA
- ○ B. Median time to recovery of prolonged cytopenia was approximately 2 months post ABECMA
- ○ C. Three patients (out of 127) underwent rescue stem cell transplantation for prolonged cytopenia after treatment with ABECMA
- ○ D. All of the above

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