

REMS PROGRAM KNOWLEDGE ASSESSMENT

Hospital Information (All Fields Required)

Hospital Name:

Address:

City:

State:

Zip Code:

Phone:

Fax:

First Name:

Last Name:

Credentials: DO MD R.Ph NP/PA Other (please specify)

Phone:

Fax:

E-mail:

Authorized Representative: Yes No

Signature:

Date (MM/DD/YYYY):

If you are the Authorized Representative for your hospital, please complete and submit the knowledge assessment to the REMS Call Center via fax to 1-844-590-0840, E-mail at KymriahREMS@ubc.com, or complete online at www.Kymriah-REMS.com. All others please complete online or send the form to your hospital's Authorized Representative. Completion of this knowledge assessment does not guarantee your hospital will be certified to administer Kymriah[®].

- 1- Kymriah[®] (tisagenlecleucel) is indicated for the treatment of:
 - A- Patients up to 25 years of age newly diagnosed B-cell acute lymphoblastic leukemia (ALL)
 - B- Patients up to 25 years of age with B-cell precursor ALL that is refractory or in 2nd or later relapse
 - C- Adult patients with newly diagnosed diffuse large B-cell lymphoma (DLBCL)
 - D- Adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy including DLBCL not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma
 - E- Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy
 - F- All except A and C
- 2- Delay Kymriah infusion if the patient has any of the following, **except**:
 - A- Active uncontrolled infection
 - B- Worsening of leukemia burden following lymphodepleting chemotherapy
 - C- Severe neutropenia and thrombocytopenia following lymphodepleting chemotherapy
 - D- Active graft versus host disease
 - E- Unresolved serious adverse reactions from preceding chemotherapies
- 3- Clinically, patients with CRS can manifest with the following signs and symptom **except**:
 - A- High grade fever
 - B- Hypotension
 - C- Hair loss
 - D- Respiratory distress
 - E- Hypofibrinogenemia
- 4- Which one of the following is true regarding the time to onset of CRS? It typically occurs:
 - A- 7-14 days following Kymriah infusion, with a median time to onset of 10 days
 - B- 7-21 days following Kymriah infusion, with a median time to onset of 10 days
 - C- Median time to onset is 3-4 days following Kymriah infusion
 - D- Rarely starts during the first week following Kymriah infusion

- 5- As a part of planning for Kymriah infusion, it is required to have on-site, immediate access (within 2 hours) to a minimum of two doses of tocilizumab on site for each patient prior to dispensing and administering Kymriah to patients:
- A- True
 - B- False
- 6- As a part of the patient and caregiver education for Kymriah, advise the patient to refrain from driving and engaging in hazardous occupations or activities (operating heavy or potentially dangerous machinery) for at least 8 weeks after receiving Kymriah:
- A- True
 - B- False
- 7- A 5-year-old male with relapsed ALL following an allogeneic transplantation was treated with Kymriah. One day following infusion, he developed high grade fever (40-41°C) with neutropenia and was hospitalized. On day 2, he developed hypotension, which improved with fluid resuscitation. He was transferred to the PICU for close observation, and later developed recurrent hypotension, mild tachypnea and hypoxia (O₂ saturation 91%). He was started on norepinephrine at a low dose and O₂ supplement via nasal cannula. All of the following are correct, **except**:
- A- The patient has symptoms consistent with cytokine release syndrome and should be managed according to the CRS management algorithm
 - B- Sepsis should be considered and treated adequately with broad spectrum antibiotics
 - C- Avoid antipyretics as they may affect CAR-T cell efficacy
 - D- Continue supportive care and close monitoring of hemodynamic, respiratory and neurological status
- 8- Neurological toxicities were observed with Kymriah, and the patient and the caregiver should be informed about this risk. All of the following are correct, **except**:
- A- May occur in the context of CRS, following the resolution of CRS or without CRS
 - B- Symptoms range from headache and confusion to encephalopathy and seizures
 - C- The majority of events were transient and self-limiting
 - D- Can be prevented with the administration of tocilizumab
- 9- Which one of the following about neurological toxicities as a result of Kymriah is correct:
- A- Perform neurological work-up as appropriate to exclude other etiologies of neurological symptoms
 - B- Management includes supportive care
 - C- Majority occurred within 8 weeks following Kymriah infusion
 - D- All of the above
- 10- A 30-year-old female with multiply relapsed DLBCL treated with Kymriah as an outpatient 2 days after completion of lymphodepleting chemotherapy. The patient and her caregiver should be advised about the following:
- A- The risk of CRS and neurological toxicities and to contact the healthcare provider if experiencing signs and symptoms associated with CRS and neurological toxicities
 - B- The patient should plan to stay within 2 hours of the treatment site for at least 4 weeks after receiving Kymriah
 - C- The patient should carry the Kymriah patient wallet card to remind them of the signs and symptoms of CRS and neurological toxicities that require immediate attention
 - D- All of the above
11. A 22-year-old male with relapsed/refractory Philadelphia chromosome negative B cell Acute Lymphoblastic Leukemia (ALL) developed grade 1 cytokine release syndrome (CRS) 6 hours after treatment with KYMRIAH, progressing to Grade 2 CRS on day 2. The patient was treated with two doses of tocilizumab, following which rapid clinical improvement was noted. On day 11, he presented with new fever and need for high oxygen therapy. His labs showed impaired renal and hepatic functions, along with coagulopathy and elevated ferritin. Given the current clinical signs and symptoms, an evaluation for Hemophagocytic Lymphohistiocytosis/Macrophage activation syndrome (HLH/MAS) should be performed.
- A- True
 - B- False



Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

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