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Tafasitamab-cxix (MONJUVI®) for Relapsed/Refractory Follicular Lymphoma

Description:

- The purpose of this PQI is to discuss clinical considerations surrounding tafasitamab-cxix (tafasitamab) treatment for patients with relapsed/refractory (R/R) follicular lymphoma (FL).

Background[1]:

- Tafasitamab is a humanized monoclonal antibody that targets and binds to CD19 antigen expressed on the surface of pre-B and mature B lymphocytes, including B-cell malignancy cells of diffuse large B-cell lymphoma (DLBCL) and FL. Tafasitamab causes malignant B-cell lysis via direct apoptosis and enhanced immune effector mechanisms, including antibody-dependent cellular cytotoxicity and antibody-dependent cellular phagocytosis.
- Tafasitamab is FDA approved for two indications in adult patients:
  - R/R FL in combination with lenalidomide and rituximab
  - R/R DLBCL in combination with lenalidomide in patients who are not eligible for autologous stem cell transplant
- Most common adverse reactions in patients with R/R FL (≥ 20% including Grade 3 or 4 laboratory abnormalities): respiratory tract infections, diarrhea, rash, fatigue, constipation, musculoskeletal pain, cough, decreased neutrophils and decreased lymphocytes
  - Infusion-related reactions (IRR): occurred in 16% of the 274 patients with FL who received tafasitamab in combination with lenalidomide and rituximab in the inMIND trial[2]; premedication regimen described below

PQI Process: Upon receipt of a new order for treatment with tafasitamab:

- **Verify diagnosis:** Adult patient with FL and disease that has progressed on at least one prior line of therapy
- **Verify premedications:** Premedications should be given 30-120 minutes prior to the first 3 tafasitamab infusions. If no reaction occurs during the first 3 infusions, premedication is optional with subsequent infusions.
  - Premedications may include:
    - Acetaminophen
    - H1 receptor antagonist
    - H2 receptor antagonist AND/OR
    - Corticosteroid
  - Emetic risk is low
- **Verify tafasitamab dosing:**
  - The recommended dose of tafasitamab is 12 mg/kg (based on actual body weight) given via IV infusion
  - Cycles 1-3: Days 1, 8, 15, 22
  - Cycles 4-12: Days 1 and 15
- **Verify rituximab dosing:**
  - Cycle 1: 375 mg/m^2 IV on days 1, 8, 15, 22
  - Cycle 2-5: 375 mg/m^2 IV on day 1

- **Verify lenalidomide dosing**:
  - Cycles 1-12: 20 mg orally once daily on days 1-21 of each 28-day cycle
  - Ensure all lenalidomide REMS requirements are met
  - Dose adjustments needed for baseline renal dysfunction
  - Ensure patient started on appropriate venous/arterial thromboembolism prophylaxis[3]
- **Preparation**
  - Tafasitamab is supplied as 200 mg vials
  - Reconstitute each 200 mg vial with 5 mL of sterile water (final concentration of 40 mg/mL). If needed, store the reconstituted solution in the vial for a maximum of 12 hours either refrigerated at 36°F to 46°F (2°C to 8°C) or room temperature at 68°F to 77°F (20°C to 25°C) before dilution.
  - Remove a volume equal to the required tafasitamab solution from a 250 mL 0.9% sodium chloride injection, USP infusion bag and discard it.
  - Slowly dilute tafasitamab into the 0.9% sodium chloride infusion bag to a final concentration of 2 to 8 mg/mL.
  - If not used immediately, store the diluted tafasitamab infusion solution refrigerated for up to 18 hours at 36°F to 46°F (2°C to 8°C) and/or at room temperature for up to 12 hours at 68°F to 77°F (20°C to 25°C). The room temperature storage includes time for infusion.
  - Protect from light during storage.
- **Administration**
  - First infusion: administer intravenously at 70 mL/h for the first 30 minutes then increase the rate so that the infusion is administered over 1.5-2.5 hours
  - Subsequent infusions: administer over 1.5-2 hours
  - Do not co-administer other medications through the same infusion line as tafasitamab
- **Monitoring**
  - Infusion-related reactions
    - Premedicate prior to starting infusion as noted above
    - Monitor patients frequently during infusion for signs and symptoms of IRR including fever, chills, rash, flushing, dyspnea, and hypertension
    - Based on the severity of the infusion-related reaction, interrupt or discontinue tafasitamab (see Supplemental Information)
  - Myelosuppression and infections
    - Monitor CBCs before each treatment cycle and throughout treatment
    - Monitor patients with neutropenia for signs of infection
    - Consider granulocyte colony-stimulating factor administration in patients with neutropenia
    - Monitor patients for signs and symptoms of infection and manage infections as appropriate
    - Consider infection prophylaxis per institutional guidelines[4]
    - Consider treatment with subcutaneous or intravenous immunoglobulin (IVIG) as appropriate
  - Embryo-fetal toxicity
    - The combination of tafasitamab with lenalidomide and rituximab is contraindicated in pregnant women because lenalidomide can cause birth defects and death of the unborn child. Refer to the lenalidomide prescribing information on use during pregnancy.[3]

- **<u>Adverse Event Management</u>**: see Supplemental Information section below

Patient-Centered Activities:

- Advise patients to alert their infusion nurse/a care team member right away if they start experiencing any of the following symptoms of IRR during or after infusion of tafasitamab:
    - Chills or shaking, itching, rash, or flushing, trouble breathing or wheezing; tongue-swelling, dizziness or feeling faint, pain in back or neck
- Patients should be encouraged to wash hands and bathe regularly, avoid crowded places, and stay away from people who are sick particularly if they are experiencing neutropenia
- Advise patients to talk to the care team if they have:
    - Fever of 100.4 F or higher, chills, cough, sore throat, painful urination, or tiredness that is worse than normal
- In the event of low platelet count, counsel patients to avoid over-the-counter medications that may increase the risk of bleeding (such as NSAIDs)
- Females of reproductive potential must not get pregnant for at least 4 weeks before starting lenalidomide, while taking lenalidomide, during any breaks (interruptions) in treatment with lenalidomide, and for at least 4 weeks after stopping lenalidomide and for 3 months after last dose of tafasitamab

References:

1) MONJUVI® (tafasitamab-cxix) [prescribing information]. Wilmington, DE: Incyte Corporation; 2025.
2) Sehn LH, Hübel K, Luminari S, et al. Tafasitamab, lenalidomide, and rituximab in relapsed or refractory follicular lymphoma (inMIND): A global, phase 3, randomised controlled trial. *Lancet*. 2026;407(10524):133-146. doi: 10.1016/S0140-6736(25)01778-7
3) REVLIMID® (lenalidomide) [prescribing information]. Summit, NJ: Celgene Corporation; 2022.
4) NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prevention and Treatment of Cancer-Related Infections V 1.2026-3.2026. © National Comprehensive Cancer Network, Inc. 2026. All rights reserved. Accessed [September 2026].

Supplemental Information:

Adverse Reaction Management

Adverse Reaction	Severity	Dosage Modification
Hematologic Toxicity	Platelets ≤ 50,000/mm^3	Hold tafasitamab-cxix (and lenalidomide), monitor CBC weekly until platelet count is ≥ 50,000/mm^3, then resume tafasitamab-cxix at the same dose (and lenalidomide at a reduced dose).
	Neutrophil count ≤ 1,000/mcL for at least 7 days **or** neutrophil count ≤ 1,000/mcL with fever (temp ≥ 100.4°F or ≥ 38°C) **or** neutrophil count < 500/mcL	Hold tafasitamab-cxix (and lenalidomide), monitor CBC weekly until neutrophil count is ≥ 1,000/mcL, then resume tafasitamab-cxix at the same dose (and lenalidomide at a reduced dose).
Infusion related reaction	Grade 2 (moderate)	Interrupt infusion immediately and manage symptoms. Once resolved or reduced to Grade 1, resume infusion at 50% rate at which reaction occurred. If no further reaction within 1 hour and vital signs are stable, may increase infusion rate every 30 minutes as tolerated to rate at which the reaction occurred.
	Grade 3 (severe)	Interrupt infusion immediately and manage symptoms. Once resolved or reduced to Grade 1, resume infusion at

		25% rate at which reaction occurred. If no further reaction within 1 hour and vital signs are stable, may increase infusion rate every 30 minutes as tolerated to a maximum of 50% rate at which the reaction occurred. Stop immediately if Grade 3 reaction returns upon rechallenge and permanently discontinue tafasitamab.
	Grade 4 (life threatening)	Stop infusion immediately and permanently discontinue