# The Medical Letter®

## on Drugs and Therapeutics

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Online Article

IN THIS ISSUE



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In Brief: Tafasitamab *(Monjuvi)* for Diffuse Large B-Cell Lymphoma

## IN BRIEF

# Tafasitamab *(Monjuvi)* for Diffuse Large B-Cell Lymphoma

Tafasitamab-cxix (*Monjuvi* – Morphosys), a CD19-directed cytolytic antibody, has received accelerated approval from the FDA for use in combination with lenalidomide *(Revlimid)* for treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from low grade lymphoma, in adults who are not eligible for autologous stem cell transplant. Accelerated approval was based on overall response rates.

**Pronunciation Key**

**Tafasitamab-cxix:** ta" fa sit' a mab *Monjuvi*: mon joo' vee

The four-letter suffix -cxix has no pronunciation or meaning; such suffixes are added to biologic drugs to distinguish reference products from their biosimilars.

**DLBCL —** DLBCL is the most common type of aggressive non-Hodgkin's lymphoma. Standard first-line treatment of DLBCL consists of the combination of rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP). Polatuzumab vedotin *(Polivy)* plus R-CHP (vincristine was substituted with polatuzumab vedotin; both drugs should not be given together because of an increased risk of neurotoxicity) is an alternative.[1] The risk of relapse is highest within one year following treatment.[2] Second-line treatment of relapsed or refractory DLBCL is generally aggressive salvage chemotherapy or autologous stem-cell transplantation.

**CLINICAL STUDIES —** Accelerated approval of tafasitamab was based on the results of an open-label, single-arm trial (L-MIND) in 81 adults with relapsed or refractory DLBCL who received 1-3 prior systemic regimens, including at least one anti-CD20 therapy, and were not candidates for high-dose chemotherapy and autologous stem-cell transplantation. Patients received tafasitamab 12 mg/kg given IV with lenalidomide (25 mg orally on days 1 to 21 of each 28-day cycle) for up to 12 cycles, followed by tafasitamab alone until disease progression occurred. After a median follow-up of 13.2 months, 60% of patients had a complete response and 18% had a partial response.[3]

**ADVERSE EFFECTS —** Myelosuppression, fatigue, anemia, diarrhea, cough, pyrexia, peripheral edema, respiratory tract infection, and decreased appetite have been reported with tafasitamab. Infusion-related reactions can occur.

**DOSAGE, ADMINISTRATION, AND COST —** Tafasitamab is given in 28-day cycles in combination with lenalidomide 25 mg for a maximum of 12 cycles, then as monotherapy until disease progression or unacceptable toxicity occurs. The recommended dosage of tafasitamab is 12 mg/kg administered IV on days 1, 4, 8, 15, and 22 in cycle 1, days 1, 8, 15, and 22 in cycles 2 and 3, and days 1 and 15 in subsequent cycles. Patients should receive acetaminophen, an antihistamine, and/or a corticosteroid before the first 3 infusions and as needed thereafter. The label specifies dosage adjustments that should be made if adverse effects occur. The wholesale acquisition cost for one dose of *Monjuvi* for an 80-kg patient is $6368.20.[4]

1. Polatuzumab vedotin (Polivy) for lymphoma. Med Lett Drugs Ther 2023; 65:e89.
2. JA Davis et al. Polatuzumab vedotin for the front-line treatment of diffuse large B-cell lymphoma: a new standard of care? J Adv Pract Oncol 2023; 14:67.
3. G Salles et al. Tafasitamab plus lenalidomide in relapsed or refractory diffuse large B-cell lymphoma (L-MIND): a multicentre, prospective, single-arm, phase 2 study. Lancet Oncol 2020; 21:978.
4. Approximate WAC. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. July 5, 2023. Reprinted with permission by First Databank, Inc. All rights reserved. ©2023. www.fdbhealth.com/policies/drug-pricing-policy.

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