RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	tafasitamab-cxix
Policy Number:	RxA.650
Drug(s) Applied:	MONJUVI®
Original Policy Date:	09/14/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

MONJUVI is a CD19-directed cytolytic antibody indicated in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT).

This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

DLBCL is the most common subtype of non-Hodgkin lymphoma (NHL), accounting for approximately one-fourth of the NHL cases diagnosed annually in the U.S. DLBCL occurrence typically increases with age, with most patients being over 60 years of age at diagnosis.

DLBCL is an aggressive NHL that typically presents as a rapidly enlarging mass in the lymph nodes in the neck or abdomen, but it may also develop in extranodal sites. DLBCL is curable in approximately 50% of patients with current frontline therapy, but patients who relapse or are refractory to frontline management have a poor prognosis.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
tafasitamab-cxix (MONJUVI®)	Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT).	12 mg/kg (actual body weight) IV on days 1, 4, 8, 15, and 22 of cycle 1; 12 mg/kg IV on days 1, 8, 15, and 22 of cycles 2 and 3; and 12 mg/kg IV on days 1 and 15 of cycle 4 and beyond until disease progression; administer in combination with lenalidomide 25 mg orally daily on days 1 to 21 for a maximum of 12 cycles. Treatment cycles are repeated every 28 days.	12 mg/kg (actual body weight) IV per dose.

Dosage Forms

- For injection: 200 mg of tafasitamab-cxix as lyophilized powder in single dose vial for reconstitution.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. DLBCL (must meet all):

1. Diagnosis of refractory or relapsed DLBCL
2. Prescribed by or in consultation with an oncologist;
3. Must be prescribed in combination with Revlimid® (lenalidomide)
4. Age ≥ 18 years;
5. Dose does not exceed 12 mg/kg (actual body weight) IV per dose.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. DLBCL (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request for a dose increase, new dose does not exceed 12 mg/kg (actual body weight) IV per dose.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
DLBCL: diffuse large B-cell lymphoma
ASCT: autologous stem cell transplant
NHL: non-Hodgkin lymphoma

APPENDIX B: Therapeutic Alternatives

Drug Name	Dosing Regimen
Polivy® (polatuzumab vedotin-piiq)	1.8 mg/kg every 21 days for 6 cycles
Kymriah® (tisagenlecleucel)	One-time infusion
Yescarta® (axicabtagene ciloleucel)	One-time infusion
Xpovio® (selinexor)	Oral administration: Days 1 and 8 of each cycle

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None.

- Boxed Warning(s):
  - None.

APPENDIX D: General Information

Treatment strategies for patients with relapsed or refractory DLBCL consist of a platinum-based salvage chemotherapy followed by high-dose chemotherapy and ASCT. However, many patients are not candidates for ASCT due to comorbidities or age, and there is no standard of care for optimal management in these patients. Therefore, treatment selection in these patients should be based on comorbidities, treatment-related toxicity, patient preference, and pathologic features of the disease.

Salvage regimens include CAR T therapy, Polivy, and bendamustine with rituximab, lenalidomide with or without rituximab, Imbruvica without or with lenalidomide and rituximab, lower intensity combination chemoimmunotherapy, single agent rituximab, and sequential single agent therapy (e.g. gemcitabine, anthracyclines, cytarabine, alkylating agents).

References

1. Monjuvi (tafasitamab-cxix) [prescribing information]. Boston, MA: Morphosys US, Inc.; July 2020. Accessed on August 24, 2020.
2. B-Cell Lymphomas (Version 4.2020). NCCN Clinical Practice Guidelines in Oncology. National Comprehensive Cancer Network (NCCN). Accessed on August 24, 2020.
3. Freeman AS and Friedberg JW. Treatment of relapsed or refractory diffuse large B- cell lymphoma. In: UpToDate. Negrin RS (Ed). Waltham, MA. 2020.S

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	08/27/2020	09/14/2020