Clinical Policy Title:	tafasitamab-cxix
Policy Number:	RxA.650
Drug(s) Applied:	Monjuvi®
Original Policy Date:	09/14/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Tafasitamab-cxix (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).

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
tafasitamab-cxix (Monjuvi®)	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) intravenous on days 1, 4, 8, 15, and 22 of cycle 1; 12 mg/kg intravenous on days 1, 8, 15, and 22 of cycles 2 and 3; and 12 mg/kg intravenous 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) intravenous 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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. DLBCL (must meet all):

1. Diagnosis of refractory or relapsed DLBCL;
2. Age ≥ 18 years;
3. Prescribed by or in consultation with an oncologist;
4. Must be prescribed in combination with Revlimid® (lenalidomide);
5. Documentation supporting that the member is not eligible for autologous stem cell transplant (ASCT).
6. Dose does not exceed 12 mg/kg (actual body weight) intravenous per dose.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. DLBCL (must meet all):

1. Member is 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 is for a dose increase, new dose does not exceed 12 mg/kg (actual body weight) intravenous 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
CAR: Chimeric antigen receptor
NCCN: National Comprehensive Cancer Network

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Polivy®	1.8 mg/kg every 21 days for 6 cycles	1.8 mg/kg intravenous every 21 days
Kymriah®	0.6 to 6 X 10^8 CAR-positive viable T-cells infused as a single-dose	Adults ≥ 18 years: 6 X 10^8 CAR-positive viable T-cells
Yescarta®	Target dose is 2 × 10^6 CAR-positive viable T cells per kg body weight intravenous	2 X 10^6 CAR-positive viable T-cells per kg of body weight (maximum dose of 2 X 10^8 CAR-positive viable T-cells) as a single intravenous dose

Xpovio®	Recommended dosage of Xpovio® is 60 mg orally on Days 1 and 3 of each week	60 mg orally twice weekly on days 1 and 3

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - None reported.

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® Prescribing Information. Boston, MA: Morphosys US, Inc.; June 2021. Available at: https://www.monjuvi.com/pi/monjuvi-pi.pdf . Accessed July 2, 2021.
2. National Comprehensive Cancer Network. B-Cell Lymphomas Version 4.2021. Available at https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf . Accessed July 2, 2021.
3. Freeman AS and Friedberg JW. Treatment of relapsed or refractory diffuse large B- cell lymphoma. In: UpToDate. Negrin RS (Ed). Waltham, MA. 2021.S. Available at: https://www.uptodate.com/contents/treatment-of-relapsed-or-refractory-follicular-lymphoma. Accessed July 2, 2021.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at https://www.clinicalkey.com/pharmacology/. Accessed July 2, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	08/27/2020	09/14/2020
Policy was reviewed: 1. Background was updated to remove "DLBCL is the most common subtype of non-Hodgkin lymphoma (NHL), accounting for approximately…" and "DLBCL is an aggressive NHL that	07/02/2021	09/14/2021

typically presents as a rapidly enlarging mass in the lymph nodes in the neck…”. 2. Dosing Information indication was updated to remove “Treatment of adult patients with”. 3. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 4. Initial Approval Criteria I.A.5 was updated to include “Documentation supporting that the member is not eligible for autologous stem cell transplant (ASCT).”. 5. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 6. Appendix A was updated to include abbreviations CAR and NCCN. 7. Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". 8. Appendix B: Therapeutic Alternatives was updated to remove inactive/unavailable drugs polatuzumab vedotin piiq, tisagenlecleucel, axicabtagene ciloleucel, and selinexor. 9. Appendix B: Therapeutic Alternatives was updated to include maximum dose for Polivy, “1.8 mg/kg intravenous every 21 days”. 10. Appendix B: Therapeutic Alternatives was updated to include specific dosing regimen and maximum dose for Kymriah, “0.6 to 6 X 108 CAR-positive viable T-cells infused as a single-dose” and “Adults ≥ 18 years: 6 X 108 CAR-positive viable T-cells” respectively. 11. Appendix B: Therapeutic Alternatives was updated to include specific dosing		

regimen and maximum dose for Yescarta, “Target dose is 2 × 106 CAR-positive viable T cells per kg body weight intravenous” and “2 X 106 CAR-positive viable T-cells per kg of body weight (maximum dose of 2 X 108 CAR-positive viable T-cells) as a single intravenous dose” respectively. 12. Appendix B: Therapeutic Alternatives was updated to include specific dosing regimen and maximum dose for Xpovio, “Recommended dosage of Xpovio® is 60 mg orally on Days 1 and 3 of each week” and “60 mg orally twice weekly on days 1 and 3” respectively. 13. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 14. References were reviewed and updated.		