Clinical Policy Title:	dostarlimab-gxly
Policy Number:	RxA.685
Drug(s) Applied:	Jemperli®
Original Policy Date:	06/10/2021
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

Jemperli® is a programmed death receptor-1 (PD-1)–blocking antibody indicated for the treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer, as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
dostarlimab (Jemperli®)	Recurrent/advanced endometrial cancer with dMMR	• Dose 1 through 4: 500 mg every 3 weeks • Subsequent dosing beginning 3 weeks after Dose 4 (Dose 5 onwards): 1000 mg every 6 weeks • Administer as an intravenous infusion over 30 minutes	1000 mg/dose

Dosage Forms

- Injection: 500 mg/10 mL (50 mg/mL) solution in a single-dose vial.

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. Endometrial Cancer (must meet all)**:**

1. Diagnosis of recurrent/advanced endometrial cancer with dMMR as confirmed by an FDA-approved test;
2. Prescribed by or in consultation with an oncologist;
3. Age 18 years or older;
4. Member has failed treatment with a platinum-containing regimen within the past 12 months, unless contraindicated or clinically significant adverse effects are experienced;

5. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 (Appendix D);
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 500 mg per dose for doses 1-4 AND 1000 mg per dose for doses 5 or greater;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Endometrial Cancer (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dosage change, request meets one of the following (a or b):*
   a. New dose does not exceed 500 mg per dose for doses 1-4 AND 1000 mg per dose for doses 5 or greater;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval Duration
Commercial: 6 months
Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
PD-1: programmed death receptor-1
FDA: Food and Drug Administration
dMMR: mismatch repair deficient
ECOG: Eastern Cooperative Oncology Group
NCCN: National Cancer Center 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	Maximum Dose
pembrolizumab (Keytruda®)	200 mg every 3 weeks or 400 mg every 6 weeks with lenvatinib 20 mg orally once daily for tumors that are not MSI-H or dMMR.	400 mg/dose

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

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None.

- Boxed Warning(s):
  - None.

APPENDIX D: General Information

- Eastern Cooperative Oncology Group (ECOG) performance status:

GRADE	ECOG PERFORMANCE STATUS
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
3	Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
4	Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
5	Dead

References

1. Jemperli® Prescribing Information. GlaxoSmithKline, LLC. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761174s000lbl.pdf. Accessed May 27, 2021.
2. Jemperli®, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed May 27, 2021.
3. Tesaro, Inc. A Phase 1 Dose Escalation and Cohort Expansion Study of TSR-042, an Anti-PD-1 Monoclonal Antibody, in Patients With Advanced Solid Tumors. Available at: https://clinicaltrials.gov/ct2/show/NCT02715284. NLM identifier: NCT02715284. Accessed May 27, 2021.
4. National Comprehensive Cancer Network. Uterine Neoplasms Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Updated May 07, 2021. Accessed May 27, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	06/10/2021	06/10/2021