Clinical Policy Title:	dostarlimab-gxly
Policy Number:	RxA.685
Drug(s) Applied:	Jemperli®
Original Policy Date:	06/10/2021
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

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

1. Diagnosis of recurrent or advanced endometrial cancer with dMMR as confirmed by an FDA-approved test;
2. Prescribed by or in consultation with an oncologist;
3. Jemperli® will be prescribed as a single agent;
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. Member is not a suitable candidate for curative surgery or radiation;
6. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1;
7. 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

All lines of business (except Medicare): 6 months

B. Solid tumor (must meet all):

1. Diagnosis of recurrent or advanced solid tumor with dMMR (e.g., breast cancer, colon cancer, gastric cancer, ovarian/fallopian tube/primary peritoneal cancer, rectal cancer, small bowel adenocarcinoma, occult primary cancer, uterine neoplasms, ampullary adenocarcinoma, esophageal and esophagogastric junction cancers);
2. Prescribed by or in consultation with an oncologist;
3. Solid tumors that have progressed on or following prior treatment and who have no satisfactory alternative treatment options;
4. Jemperli® will be prescribed as a single agent;
5. 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

All lines of business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Indications in section I (must meet all)**:**

1. Member is currently receiving medication, excluding manufacturer samples;
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. 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

All lines of business (except Medicare): 6 months

References

1. 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 August 21, 2023.
2. National Comprehensive Cancer Network. Uterine Neoplasms. Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed August 21, 2023.
3. National Comprehensive Cancer Network. Breast Cancer. Version 4.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed August 21, 2023.
4. National Comprehensive Cancer Network. Colon Cancer. Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed August 21, 2023.
5. National Comprehensive Cancer Network. Esophageal and Esophagogastric Junction Cancers. Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf. Accessed August 21, 2023.
6. National Comprehensive Cancer Network. Gastric Cancer. Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf. Accessed August 21, 2023.
7. National Comprehensive Cancer Network. Occult Primary. Version 3.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/occult.pdf. Accessed August 21, 2023.
8. National Comprehensive Cancer Network. Ovarian Cancer/Fallopian Tube Cancer/primary peritoneal cancer. Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed August 21, 2023.
9. National Comprehensive Cancer Network. Rectal Cancer. Version 4.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Accessed August 21, 2023.
10. National Comprehensive Cancer Network. Small Bowel Adenocarcinoma. Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/small_bowel.pdf. Accessed August 21, 2023.
11. National Comprehensive Cancer Network. Ampullary Adenocarcinoma. Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ampullary.pdf. Accessed August 21, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	06/10/2021	06/10/2021
Policy was revised 1. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, Solid tumor. 2. References were reviewed and updated.	02/03/2022	04/18/2022

Policy was reviewed: 1. Initial Approval Criteria, I.A.4 and I.B.6: Updated to include new prescribing criteria Jemperli® will be prescribed as a single agent. 2. Initial Approval Criteria, I.A.6: Updated to include new criteria for indication Endometrial Cancer, Member is not a suitable candidate for curative surgery or radiation. 3. Initial Approval Criteria, I.B.1: Updated diagnosis from solid tumor to recurrent or advanced solid tumor with dMMR. 4. Initial Approval Criteria, I.B.1: Updated to remove prior diagnostic criteria "Hepatobiliary cancer". Also to include new diagnostic criteria ampullary adenocarcinoma, esophageal and esophagogastric junction cancers. 5. Initial Approval Criteria, I.B.4 was removed for, Disease is recurrent or advanced, dMMR (i.e., disease is indicative of MMR gene mutation or loss of expression), since criteria was added into initial approval criteria I.B.1. 6. References were reviewed and updated.	04/03/2023	04/13/2023
Policy was reviewed: 1. Updated Lines of Business Policy Applies to All lines of business (except Medicare). 2. Initial Approval Criteria, I.A and I.B: Updated to remove prior age criteria "Age ≥ 18 years". 3. Approval duration was updated to All Lines of Business (except Medicare): 6 months. 4. Continued Therapy Approval Criteria, II.A.1: updated to “Member is currently receiving…”. 5. References were reviewed and updated.	08/21/2023	10/19/2023