

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – Programmed Death Receptor-1) – Jemperi Utilization Management Medical Policy

- Jemperi™ (dostarlimab intravenous infusion – GlaxoSmithKline)

REVIEW DATE: 05/13/2026

OVERVIEW

Jemperi, a programmed death receptor-1 blocking antibody, is indicated for the treatment of adults with recurrent or advanced:¹

- **Endometrial cancer:**
 - As a single agent in disease that is mismatch repair deficient (dMMR) as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen in any setting and are not candidates for curative surgery or radiation.
 - In combination with carboplatin and paclitaxel, followed by Jemperi as a single agent.
- **Solid tumors** that are dMMR as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Guidelines

The use of Jemperi is recommended across multiple National Comprehensive Cancer Network (NCCN) guidelines and the NCCN Compendium.²⁻¹⁷ Recommendations with a category of evidence of 2B or higher support the approval criteria outlined below.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Jemperi. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Jemperi as well as the monitoring required for adverse events and long-term efficacy, approval requires Jemperi to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Jemperi is recommended in those who meet one of the following criteria:

FDA-Approved Indications

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1. **Endometrial Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
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Note: If the tumor is Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors, see MSI-H or dMMR Solid Tumors criteria.

- A) Patient is ≥ 18 years of age; AND
- B) Patient has recurrent, advanced, or metastatic disease; AND
- C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve ONE of the following regimens (A or B):

- A) Monotherapy: Approve 500 mg administered intravenously no more frequently than once every 3 weeks for 4 doses, then 1,000 mg intravenously no more frequently than once every 6 weeks; OR
- B) In Combination with Chemotherapy: Approve 500 mg administered intravenously no more frequently than once every 3 weeks for 6 doses, then 1,000 mg intravenously no more frequently than once every 6 weeks.

2. Mismatch Repair Deficient (dMMR) or Microsatellite Instability-High (MSI-H) Solid Tumors.

Approve for 1 year if the patient meets BOTH of the following (A and B):

Note: Examples of solid tumors include ampullary adenocarcinoma, biliary tract cancer, breast cancer, endometrial carcinoma, esophageal and esophagogastric junction cancer, gastric cancer, hepatocellular cancer, occult primary, ovarian cancer, and pancreatic adenocarcinoma.

- A) Patient is ≥ 18 years of age; AND
- B) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 500 mg administered intravenously no more frequently than once every 3 weeks for 4 doses, then 1,000 mg intravenously no more frequently than once every 6 weeks.

Other Uses with Supportive Evidence

3. Anal Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, Band C):

- A) Patient is ≥ 18 years of age; AND
- B) Patient meets ONE of the following (i or ii):
 - i. Patient meets BOTH of the following (a and b):
 - a) Patient has locally recurrent or progressive disease; AND
 - b) Medication is administered before proceeding to abdominoperineal resection; OR
 - ii. Patient has metastatic disease; AND
- C) Medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 500 mg administered intravenously no more frequently than once every 3 weeks for 4 doses, then 1,000 mg intravenously no more frequently than once every 6 weeks.

4. Colon, Rectal, or Appendiceal Cancer. Approve for the duration noted if the patient meets ALL of the following (A, B, C, and D):

Note: If the tumor is Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors, see MSI-H or dMMR Solid Tumors criteria.

- A) Patient is ≥ 18 years of age; AND
- B) The disease is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (tumor mutation burden > 50 mutations/megabase); AND
- C) Patient meets ONE of the following (i or ii):

- i. Approve for 6 months total if the medication is used for neoadjuvant therapy; OR
 - ii. Approve for 1 year if the patient has advanced or metastatic disease; AND
- D) Medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 500 mg administered intravenously no more frequently than once every 3 weeks for 4 doses, then 1,000 mg intravenously no more frequently than once every 6 weeks.

5. Small Bowel Adenocarcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

Note: If the tumor is Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors, see MSI-H or dMMR Solid Tumors criteria.

- A) Patient is ≥ 18 years of age; AND
- B) The disease is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (tumor mutation burden > 50 mutations/megabase); AND
- C) Patient has advanced or metastatic disease; AND
- D) The medication is prescribed by or consultation with an oncologist.

Dosing. Approve 500 mg administered intravenously no more frequently than once every 3 weeks for 4 doses, then 1,000 mg intravenously no more frequently than once every 6 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Jemperli is not recommended in the following situations:

- 1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

- 1. Jemperli intravenous infusion [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; September 2025.
- 2. The NCCN Drugs and Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed April 28, 2026. Search term: dostarlimab.
- 3. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 2.2026 – November 14, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed April 28, 2026.
- 4. The NCCN Occult Primary (Cancer of Unknown Primary [CUP]) Clinical Practice Guidelines in Oncology (version 1.2026 – October 21, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed April 28, 2026.
- 5. The NCCN Gastric Cancer Clinical Practice Guidelines in Oncology (version 2.2026 – January 21, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed April 28, 2026.
- 6. The NCCN Esophageal and Esophagogastric Junction Cancers Clinical Practice Guidelines in Oncology (version 2.2026 – January 21, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed April 28, 2026.
- 7. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 2.2026 – February 27, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed April 28, 2026.
- 8. The NCCN Ampullary Adenocarcinoma Clinical Practice Guidelines in Oncology (version 2.2026 – February 10, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed April 28, 2026.
- 9. The NCCN Ovarian Cancer including Fallopian Tube and Primary Peritoneal Cancer Clinical Practice Guidelines in Oncology (version 4.2026 – April 10, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed April 28, 2026.
- 10. The NCCN Hepatocellular Carcinoma Clinical Practice Guidelines in Oncology (version 1.2026 – March 10, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed April 28, 2026.
- 11. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 2.2026 – April 7, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed April 28, 2026.

12. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 2.2026 – April 7, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed April 28, 2026.
13. The NCCN Small Bowel Adenocarcinoma Clinical Practice Guidelines in Oncology (version 2.2026 April 7, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed April 28, 2026.
14. The NCCN Biliary Tract Cancers Clinical Practice Guidelines in Oncology (version 1.2026 – March 10, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed April 28, 2026.
15. The NCCN Pancreatic Adenocarcinoma Clinical Practice Guidelines in Oncology (version 2.2026 – April 22, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed April 28, 2026.
16. The NCCN Anal Carcinoma Clinical Practice Guidelines in Oncology (version 2.2026 – April 7, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed April 28, 2026.
17. The NCCN Appendiceal Neoplasms and Cancers Clinical Practice Guidelines in Oncology (version 2.2026 – April 10, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed April 28, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Colon, Rectal, or Appendiceal Cancer: Patient has DNA polymerase epsilon/delta (POLE/POLD1) mutation added as new option for approval. Patient has mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) disease changed from requirement to an option for approval. Small Bowel Adenocarcinoma: Patient has DNA polymerase epsilon/delta (POLE/POLD1) mutation added as new option for approval. Patient has mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) disease changed from requirement to an option for approval.	05/08/2024
Update	10/15/2024: Updated Overview section with new endometrial indication for Jemperli. No criteria changes.	NA
Annual Revision	Anal Carcinoma: New condition of approval was added.	05/14/2025
Early Annual Revision	Mismatch Repair Deficient (dMMR) or Microsatellite Instability-High (MSI-H) Solid Tumors: The Note was modified to “Examples of solid tumors include ampullary adenocarcinoma, biliary tract cancer, breast cancer, endometrial carcinoma, esophageal and esophagogastric junction cancer, gastric cancer, hepatocellular cancer, occult primary, ovarian cancer, and pancreatic adenocarcinoma.” Previously stated, “Examples of solid tumors include ampullary adenocarcinoma, biliary tract cancer, breast cancer, esophageal and esophagogastric junction cancer, gastric cancer, hepatocellular cancer, and ovarian cancer.” The requirements that the patient has progressed on or after prior treatment and according to the prescriber, and that the patient does not have any satisfactory alternative treatment options have been removed. Anal Carcinoma: The option that the patient has NOT received prior immunotherapy was removed as an option for approval. Colon, Rectal, or Appendiceal Cancer: The patient has DNA polymerase epsilon/delta (POLE/POLD1) mutation was modified to the disease is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (tumor mutation burden > 50 mutations/megabase). The patient has advanced or metastatic disease was removed as a requirement for approval. The option to approve for 1 year if the medication is used for primary or subsequent therapy was modified to approve for 1 year if the patient has advanced or metastatic disease. Small Bowel Adenocarcinoma: The patient has DNA polymerase epsilon/delta (POLE/POLD1) mutation was modified to the disease is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (tumor mutation burden > 50 mutations/megabase). The option that the medication is used as initial therapy and the patient has received adjuvant oxaliplatin or the patient has a contraindication to oxaliplatin was removed. The medication is used as subsequent therapy and the patient has NOT received oxaliplatin in the adjuvant setting and the patient does NOT have contraindication to oxaliplatin was removed as an option for approval.	11/19/2025

HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	Endometrial Cancer: A Note was added to refer to Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors indication if the patient has MSI-H or dMMR solid tumors. Anal Carcinoma: The option for approval that the medication is used as subsequent therapy when the patient has metastatic disease was removed. The requirement that the medication is used as a single agent was removed. Colon, Rectal, or Appendiceal Cancer: A Note was added to refer to Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors indication if the patient has MSI-H or dMMR solid tumors. The option that the patient has mismatched repair deficient (dMMR) or microsatellite instability-high disease was removed. Small Bowel Adenocarcinoma: A Note was added to refer to Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors indication if the patient has MSI-H or dMMR solid tumors. The option that the patient has mismatch repair deficient (dMMR) or microsatellite instability-high disease was removed.	05/13/2026