Utilization Review Policy 254

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

- Jemperli™ (dostarlimab intravenous infusion – GlaxoSmithKline)

EFFECTIVE DATE: 09/01/2021
REVIEW DATE: 11/19/2025

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Jemperli, 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 Jemperli as a single agent.
- **Solid tumors**, that is 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.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Jemperli. 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 Jemperli as well as the monitoring required for adverse events and long-term efficacy, approval requires Jemperli to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. Endometrial Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
- **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.

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2. Mismatch Repair Deficient (dMMR) or Microsatellite Instability-High (MSI-H) Solid Tumors. Approve for 1 year if the patient meets ALL 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

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3. Anal Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
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 meets ALL of the following (a, b, and c):
    a) Patient has metastatic disease; AND
    b) Medication is used as subsequent therapy; AND
C) The medication is used as a single agent; 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.

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4. Colon, Rectal, or Appendiceal Cancer. Approve for the duration noted if the patient meets ALL of the following (A, B, C, and D):
A) Patient is ≥ 18 years of age; AND
B) Patient meets ONE of the following (i or ii):
  i. Patient has mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) disease; OR
  ii. 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 medication 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.

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

A) Patient is ≥ 18 years of age; AND

B) Patient meets ONE of the following (i or ii):

i. Patient has mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) disease; OR

ii. 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. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed November 12, 2025. Search term: dostarlimab.
3. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 1.2026 – November 4, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed November 12, 2025.
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 November 12, 2025.
5. The NCCN Gastric Cancer Clinical Practice Guidelines in Oncology (version 3.2025 – August 22, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed November 12, 2025.
6. The NCCN Esophageal and Esophagogastric Junction Cancers Clinical Practice Guidelines in Oncology (version 4.2025 – August 22, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed November 12, 2025.
7. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 5.2025 – October 16, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed November 12, 2025.
8. The NCCN Ampullary Adenocarcinoma Clinical Practice Guidelines in Oncology (version 2.2025 – January 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed November 12, 2025.
9. The NCCN Ovarian Cancer including Fallopian Tube and Primary Peritoneal Cancer Clinical Practice Guidelines in Oncology (version 3.2025 – July 16, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed November 12, 2025.
10. The NCCN Hepatocellular Carcinoma Clinical Practice Guidelines in Oncology (version 2.2025 – October 22, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed November 12, 2025.
11. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 5.2025 – October30, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed November12, 2025.

12. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 4.2025 – October 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed November 12, 2025.
13. The NCCN Small Bowel Adenocarcinoma Clinical Practice Guidelines in Oncology (version 4.2025 – October 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed November 12, 2025.
14. The NCCN Biliary Tract Cancers Clinical Practice Guidelines in Oncology (version 2.2025 – July 2, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed November 12, 2025.
15. The NCCN Pancreatic Adenocarcinoma Clinical Practice Guidelines in Oncology (version 2.2025 – February 3, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed November 12, 2025.
16. The NCCN Anal Carcinoma Clinical Practice Guidelines in Oncology (version 5.2025 – October 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed November 12, 2025.
17. The NCCN Appendiceal Neoplasms and Cancers Clinical Practice Guidelines in Oncology (version 1.2026 – October 3, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed November 12, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Endometrial Cancer:** The requirements that the patient has mismatch repair deficient disease and patient has tried a platinum containing regimen were removed. Requirement that the patient has recurrent, advanced, or metastatic disease was added. **Mismatch Repair Deficient (dMMR) or Microsatellite Instability-High (MSI-H) Solid Tumors:** Colon cancer and rectal cancer were removed from the examples in the Note. **Colon, Rectal, and Appendiceal Cancer:** New condition of approval was added.	05/10/2023
Selected Revision	**Endometrial Cancer:** Added descriptor "no more frequently than" in two places in dosing regimen and labeled this regimen "Monotherapy". Added In Combination with Chemotherapy dosing regimen. **Mismatch Repair Deficient (dMMR) or Microsatellite Instability-High (MSI-H) Solid Tumors:** Add descriptor "no more frequently than" in two places in dosing regimen. **Colon, Rectal, or Appendiceal Cancer:** Add descriptor "no more frequently than" in two places in dosing regimen. **Small Bowel Adenocarcinoma:** Add descriptor "no more frequently than" in two places in dosing regimen.	08/16/2023
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
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024
Annual Revision	**Anal Carcinoma:** New condition of approval was added.	05/14/2025
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/15/2025
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, the patient does not have any satisfactory alternative treatment options have been removed. **Anal Carcinoma:** The patient has NOT received prior immunotherapy and the Note: Examples of immunotherapy include Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), and Libtayo (cemiplimab intravenous infusion) was removed as an option for approval.	11/19/2025

	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.	