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: 05/14/2025

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** 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, as a single agent.
- **Endometrial cancer** 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, B, C, and D):
Note: Examples of solid tumors include ampullary adenocarcinoma, biliary tract cancer, breast cancer, esophageal and esophagogastric junction cancer, gastric cancer, hepatocellular cancer, and ovarian cancer.
A) Patient is ≥ 18 years of age; AND
B) Patient has progressed on or after prior treatment; AND
C) According to the prescriber, the patient does not have any satisfactory alternative treatment options; AND
D) 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) Patient has NOT received prior immunotherapy; AND
    Note: Examples of immunotherapy include Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), and Libtayo (cemiplimab intravenous infusion).
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, D, and E):
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. Patient has DNA polymerase epsilon/delta (POLE/POLD1) mutation; AND

C) Patient has advanced or metastatic disease; AND
D) 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 medication is used for primary or subsequent therapy; AND
E) 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, D, and E):
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. Patient has DNA polymerase epsilon/delta (POLE/POLD1) mutation; AND
C) Patient has advanced or metastatic disease; AND
D) Patient meets ONE of the following (i or ii):
  i. Patient meets BOTH of the following (a and b):
    a) Jemperli will be used as initial therapy; AND
    b) Patient meets ONE of the following [(1) or (2)]:
      (1) Patient has received adjuvant oxaliplatin; OR
      (2) Patient has a contraindication to oxaliplatin; OR
  ii. Patient meets ALL of the following (a, b, and c):
    a) Jemperli is used as subsequent therapy; AND
    b) Patient has NOT received oxaliplatin in the adjuvant setting; AND
    c) Patient does NOT have contraindications to oxaliplatin; AND
E) 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; August 2024.
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3. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 3.2025 – March 7, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 6, 2025.
4. The NCCN Occult Primary (Cancer of Unknown Primary [CUP]) Clinical Practice Guidelines in Oncology (version 2.2025 – September 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 6, 2025.

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6. The NCCN Esophageal and Esophagogastric Junction Cancers Clinical Practice Guidelines in Oncology (version 3.2025 – April 22, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 6, 2025.
7. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 4.2025 – April 17, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 6, 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 May 6, 2025.
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12. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – March 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 6, 2025.
13. The NCCN Small Bowel Adenocarcinoma Clinical Practice Guidelines in Oncology (version 3.2025 – March 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 6, 2025.
14. The NCCN Biliary Tract Cancers Clinical Practice Guidelines in Oncology (version 1.2025 – March 20, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 6, 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 May 6, 2025.
16. The NCCN Anal Carcinoma Clinical Practice Guidelines in Oncology (version 3.2025 – March 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 6, 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