Utilization Review Policy 254

POLICY: Oncology (Injectable – Programmed Death Receptor-1) – Jemperli
- Jemperli™ (dostarlimab intravenous infusion – GlaxoSmithKline)

EFFECTIVE DATE: 09/01/2021
REVIEW DATE: 05/10/2023; selected revision 08/16/2023

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Jemperli, a programmed death receptor-1 blocking antibody, is indicated for the treatment of adults withrecurrent 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** that is dMMR as determined by an FDA-approved test or microsatellite instability-high (MSI-H), in combination with carboplatin and paclitaxel, followed by Jemperli as a single agent.
- **Solid tumors**, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options.

Guidelines

Jemperli is addressed in the National Comprehensive Cancer Network guidelines:*

- **Ampullary Adenocarcinoma:** Guidelines (version 1.2023 – April 27, 2023) recommend Jemperli as subsequent therapy for MSI-H/dMMR tumors in patients whose cancer has progressed on or following prior treatment and who have no satisfactory alternative treatment options.
- **Biliary Tract Cancer:** Guidelines (version 1.2023 – March 10, 2023) recommend Jemperli for the subsequent treatment of MSI-H/dMMR gallbladder cancer, intrahepatic cholangiocarcinoma, and extrahepatic cholangiocarcinoma in patients whose cancer has progressed on or following prior treatment and who have no satisfactory alternative treatment options (category 2B).[2,14]
- **Breast Cancer:** Guidelines (version 4.2023 – March 23, 2023) recommend Jemperli as subsequent therapy for MSI-H/dMMR tumors in patients whose cancer has progressed on or following prior treatment and who have no satisfactory alternative treatment options.[2,7]
- **Colon Cancer:** Guidelines (version 2.2023 – April 25, 2023) recommend Jemperli as neoadjuvant therapy for MSI-H/dMMR colon cancer, and primary or subsequent therapy for MSI-H/dMMR colon cancer or appendiceal adenocarcinoma.[2,11]
- **Esophageal and Esophagogastric Junction Cancers:** Guidelines (version 2.2023 – March 10, 2023) recommend Jemperli as subsequent therapy for MSI-H/dMMR tumors in patients whose cancer has progressed on or following prior treatment and who have no satisfactory alternative treatment options.[2,6]
- **Gastric Cancer:** Guidelines (version 1.2023 – March 10, 2023) recommend Jemperli as subsequent therapy for MSI-H/dMMR tumors in patients whose cancer has progressed on or following prior treatment and who have no satisfactory alternative treatment options.[2,5]
- **Hepatocellular Carcinoma:** Guidelines (version 1.2023 – March 10, 2023) recommend Jemperli for the subsequent treatment of MSI-H/dMMR hepatocellular carcinoma in patients whose cancer has progressed on or following prior treatment and who have no satisfactory alternative treatment options (category 2B).[2,10]

- **Occult Primary:** Guidelines (version 3.2023 – December 21, 2022) recommend Jemperli as a single agent for dMMR/MSI-H tumors in symptomatic patients with performance status of 1 or 2, or asymptomatic patients with performance status of 0, in a variety of solid tumors.[3,4]
- **Ovarian Cancer:** Guidelines (version 1.2023 – December 22, 2022) recommend Jemperli as subsequent therapy for MSI-H/dMMR epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer, carcinosarcoma, clear cell or mucinous carcinoma of the ovary, grade 1 endometrioid carcinoma, and low grade serous carcinoma in patients with recurrent or advanced tumors.[2,9]
- **Rectal Cancer:** Guidelines (version 2.2023 – April 25, 2023) recommend Jemperli as neoadjuvant, primary, or subsequent therapy for MSI-H/dMMR disease.[2,12]
- **Small Bowel Adenocarcinoma:** Guidelines (version 1.2023 – January 9, 2023) recommend Jemperli as initial therapy for MSI-H/dMMR disease in patients who received oxaliplatin in the adjuvant setting or have a contraindication to oxaliplatin.[2,13] Jemperli is recommended for the subsequent treatment of MSI-H/dMMR disease in patients with no prior adjuvant oxaliplatin use or a contraindication to oxaliplatin.
- **Uterine Neoplasms:** Guidelines (version 2.2023 – April 28, 2023) recommend Jemperli for primary or adjuvant treatment, and for first- and second-line treatment of advanced, recurrent, or metastatic endometrial carcinoma.[2,3]

[*]All are category 2A recommendations unless otherwise noted.

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.

---

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, breast cancer, esophageal and esophagogastric junction cancer, gastric cancer, hepatobiliary 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

---

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

---

4. 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 has mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) disease; 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; July 2023.
2. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 2, 2023. Search term: dostarlimab.
3. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 2.2023 – April 28, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 7, 2023.
4. The NCCN Occult Primary (Cancer of Unknown Primary [CUP]) Clinical Practice Guidelines in Oncology (version 3.2023 – December 21, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 2, 2023.
5. The NCCN Gastric Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – March 10, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 2, 2023.
6. The NCCN Esophageal and Esophagogastric Junction Cancers Clinical Practice Guidelines in Oncology (version 2.2023 – March 10, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 2, 2023.
7. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 4.2023 – March 23, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 2, 2023.
8. The NCCN Ampullary Adenocarcinoma Clinical Practice Guidelines in Oncology (version 1.2023 – April 27, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 3, 2023.
9. The NCCN Ovarian Cancer including Fallopian Tube and Primary Peritoneal Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – December 22, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 2, 2023.
10. The NCCN Hepatocellular Carcinoma Clinical Practice Guidelines in Oncology (version 1.2023 – March 10, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 2, 2023.
11. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 2.2023 – April 25, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 3, 2023.
12. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 2.2023 – April 25, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 3, 2023.
13. The NCCN Small Bowel Adenocarcinoma Clinical Practice Guidelines in Oncology (version 1.2023 – January 9, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 2, 2023.
14. The NCCN Biliary Tract Cancers Clinical Practice Guidelines in Oncology (version 1.2023 – March 10, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 2, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Mismatch Repair Deficient (dMMR) or Microsatellite Instability-High (MSI-H) Solid Tumors.** Added Note with examples of solid tumors. **Small Bowel Adenocarcinoma.** Added new condition of approval.	05/04/2022
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.	05/10/2023

	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.	
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