PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 05/04/2022

OVERVIEW

Jemperli, a programmed death receptor-1 blocking antibody, is indicated for the treatment of adults with mismatch repair deficient (dMMR), recurrent or advanced:[1]

- **Endometrial cancer**, as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen.
- **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 1.2022 – March 9, 2022) recommend Jemperli as subsequent therapy for microsatellite instability-high (MSI-H)/dMMR tumors in patients whose cancer has progressed on or following prior treatment and who have no satisfactory alternative treatment options.
- **Breast Cancer:** Guidelines (version 2.2022 – December 20, 2021) 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 1.2022 – February 25, 2022) recommend Jemperli as subsequent therapy for MSI-H/dMMR colon cancer or appendiceal adenocarcinoma following previous oxaliplatin-, irinotecan-, and/or fluoropyrimidine-based therapy.[2,11]
- **Esophageal and Esophagogastric Junction Cancers:** Guidelines (version 2.2022 – February 11, 2022) 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 2.2022 – January 11, 2022) 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]
- **Hepatobiliary Cancer:** Guidelines (version 1.2022 – March 29, 2022) recommend Jemperli for the subsequent treatment of MSI-H/dMMR hepatocellular carcinoma, 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).[2,10]
- **Occult Primary:** Guidelines (version 1.2022 – September 2, 2021) 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 1.2022 – January 18, 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 1.2022 – February 25, 2022) recommend Jemperli as subsequent therapy for MSI-H/dMMR disease following previous oxaliplatin-, irinotecan-, and/or fluoropyrimidine-based therapy.[2,12]
- **Small Bowel Adenocarcinoma:** Guidelines (version 1.2022 – March 9, 2022) 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 4.2021 – September 3, 2021) recommend Jemperli for the second-line treatment of advanced or recurrent MSI-H/dMMR endometrial carcinoma that has progressed on or following prior treatment with a platinum-containing regimen.[2,3]

* All are category 2A recommendations unless otherwise noted.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Jemperli. 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, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has mismatch repair deficient (dMMR) disease; AND
   - **C)** Patient has tried a platinum-containing regimen; AND
     Note: Examples of platinum agents include cisplatin and carboplatin.
   - **D)** The medication is prescribed by or in consultation with an oncologist.

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, colon cancer, esophageal and esophagogastric junction cancer, gastric cancer, hepatobiliary cancer, ovarian cancer, and rectal 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.

Other Uses with Supportive Evidence

3. **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.

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 2021.
2. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed April 26, 2022. Search term: dostarlimab.
3. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 1.2022 – November 4, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed April 26, 2022.
4. The NCCN Occult Primary (Cancer of Unknown Primary [CUP]) Clinical Practice Guidelines in Oncology (version 1.2022 – September 2, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed April 26, 2022.
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6. The NCCN Esophageal and Esophagogastric Junction Cancers Clinical Practice Guidelines in Oncology (version 2.2022 – February 11, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed April 26, 2022.
7. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – December 20, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed April 26, 2022.
8. The NCCN Ampullary Adenocarcinoma Clinical Practice Guidelines in Oncology (version 1.2022 – March 9, 2022). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed April 26, 2022.
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12. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 1.2022 – February 25, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed April 26, 2022.
13. The NCCN Small Bowel Adenocarcinoma Clinical Practice Guidelines in Oncology (version 1.2022 – March 9, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed April 26, 2022.