

CLINICAL GUIDELINES FOR MEDICAL NECESSITY

MEDICAL ONCOLOGY

Dostarlimab-gxly (Jemperli®)

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Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Please refer to the CMS website at <http://www.cms.gov> for additional information.

Note: For Medicaid members/enrollees, circumstances when state Medicaid coverage provisions conflict with the coverage provisions within this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Dostarlimab-gxly (Jemperli): Discussion

Dostarlimab-gxly is a programmed death receptor-1 (PD-1)-blocking antibody. It is a humanized monoclonal antibody that binds to the protein PD-1 on the surface of immune cells called T cells. It works by keeping cancer cells from suppressing the immune system. This allows the immune system to attack and kill the cancer cells. ^{1,2}

Upregulation of PD-1 ligands occurs in some tumors, and signaling through this pathway can contribute to the inhibition of active T-cell immune surveillance of tumors. PD-L1 and PD-L2 are ligands of PD-1. The binding of these ligands to the PD-1 receptor found on T cells inhibits T-cell growth and cytokine production. Dostarlimab-gxly blocks or reverses PD-L1 overexpression. ²

Dostarlimab-gxly can cause immune-mediated adverse reactions (IMARS), which can be severe or fatal and can occur in any organ system or tissue. These reactions can occur at any time after starting a PD-1 or PD-L1-blocking antibody. While immune-mediated adverse reactions usually present during treatment with PD-1/PD-L1-blocking antibodies, they can also manifest after discontinuation of PD-1/PD-L1-blocking antibodies. The median time to onset of IMARs with anti-PD-1/PD-L1 antibodies is typically between 1 and 6 months; however, IMARs again may present as late as 41 months after treatment initiation. For ipilimumab (anti-CTLA-4), dermatologic IMARs typically present after 2–3 weeks of treatment, while GI and hepatic IMARs appear after 6–7 weeks and some endocrinopathies can appear 9 weeks or later after immunotherapy. ²

Dostarlimab-gxly is approved by the Food and Drug Administration (FDA) for the treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced:

1. Endometrial cancer 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; OR

2. Solid tumors 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 tumor response rate and durability of response.²

The National Comprehensive Cancer Network (NCCN) endorses dostarlimab-gxly for the following diseases: ampullary adenocarcinoma, biliary tract cancers, breast cancer, colon cancer, esophageal and esophagogastric junction cancers, gastric cancer, hepatocellular carcinoma, occult primary, ovarian, fallopian tube, primary peritoneal cancer, pancreatic adenocarcinoma, rectal cancer, small bowel adenocarcinoma, and uterine neoplasms^{3,4,5,6,7,8,9,10,11,12,13,14,15}

Dostarlimab-gxly: Definitions

- **Deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H)** - when the microsatellite DNA segments in cancer cells show changes (mutations), this indicates that the tumor cells are deficient in the repair of the mismatch errors. These cancers have microsatellite instability (also called MSI-High, MSI-H, or mismatch repair deficiency, dMMR).
- **Food and Drug Administration (FDA)** - The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
- **Immune checkpoint inhibitors (ICIs)** - Immunotherapy drugs called immune checkpoint inhibitors work by blocking checkpoint proteins from binding with their partner proteins. This prevents the "off" signal from being sent, allowing the T cells to kill cancer cells. One such drug acts against a checkpoint protein called CTLA-4. Other immune checkpoint inhibitors act against a checkpoint protein called PD-1 or its partner protein PD-L1.¹⁶
- **Immune-mediated adverse reactions (IMARs)** - Immune checkpoint proteins, such as cytotoxic T-lymphocyte antigen-4 and programmed death-1, are part of the normal immune system and regulate immune activation. Treatment with inhibitors for these checkpoint proteins can result in adverse reactions that present similarly to other conditions. These immune-mediated adverse reactions (IMARs) are most commonly gastrointestinal, respiratory, endocrine, or dermatologic. More rarely, neurologic, ocular, cardiovascular, hematologic, and renal IMARs can occur.¹⁷
- **National Comprehensive Cancer Network (NCCN)** - An alliance of 32 leading cancer centers devoted to patient care, research, and education. The NCCN guidelines are utilized for Radiation Therapy and Medical Oncology standards. NCCN consensus clinical standards are periodically updated and NantHealth, Inc. reviews these and updates its policies within a timely manner.
- **Programmed cell death protein 1 (PD-1)/Programmed cell death-ligand 1 (PD-L1)** - Checkpoint proteins, such as PD-L1 on tumor cells and PD-1 on T cells, help keep immune responses in check. The binding of PD-L1 to PD-1 keeps T cells from

killing tumor cells in the body. Blocking the binding of PD-L1 to PD-1 with an immune checkpoint inhibitor (anti-PD-L1 or anti-PD-1) allows the T cells to kill tumor cells. ¹⁶

Dostarlimab-gxly: Policy

Dostarlimab-gxly will be considered for coverage when the following criteria are met:

Solid Tumors (for indications not covered below)

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. No disease progression on prior therapy with a PD-1 or PD-L1; AND
4. Mismatch repair deficient (dMMR) recurrent or advanced disease that has progressed on or following prior treatment and who has no satisfactory alternative treatment options ²

Ampullary Adenocarcinoma

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. No disease progression on prior therapy with a PD-1 or PD-L1; AND
4. Subsequent therapy as a single agent for disease progression if microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) for recurrent or advanced tumors that have progressed on or following prior treatment and have no satisfactory alternative treatment options ³

Biliary Tract Cancers (Extrahepatic Cholangiocarcinoma, Gallbladder Cancer, and Intrahepatic Cholangiocarcinoma)

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. No disease progression on prior therapy with a PD-1 or PD-L1; AND
4. Subsequent treatment as a single agent for progression on, or after, systemic treatment for unresectable or resected gross residual (R2) disease, or metastatic disease that is microsatellite instability-high (MSI-H) and/or deficient mismatch repair (dMMR) and has no satisfactory alternative treatment options ⁴

Breast Cancer

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. No disease progression on prior therapy with a PD-1 or PD-L1; AND

4. Single-agent therapy for invasive breast cancer (not inflammatory histology) for recurrent unresectable (local or regional) or stage IV (M1) disease that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) and has progressed on or following prior treatment and has no satisfactory alternative treatment options for one of the following:
 - a) As third-line therapy and beyond for hormone receptor positive (HR+) and human epidermal growth factor receptor 2 (HER2)-negative disease with visceral crisis or endocrine therapy refractory, or for triple negative breast cancer (TNBC)
 - b) Fourth line and beyond for HER2-positive disease; OR
5. Single-agent therapy for inflammatory breast cancer for patients who had no response to preoperative systemic therapy, or recurrent unresectable (local or regional), or stage IV (M1) disease that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) and has progressed on or following prior treatment and has no satisfactory alternative treatment options for one of the following:
 - a) Third-line therapy and beyond for hormone receptor positive (HR+) and human epidermal growth factor receptor 2 (HER2)-negative with visceral crisis or endocrine therapy refractory, or for triple negative breast cancer (TNBC)
 - b) Fourth line and beyond for HER2-positive disease ⁵

Colon Cancer

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. No disease progression on prior therapy with a PD-1 or PD-L1; AND
4. Treatment as a single agent for deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] disease only for one of the following:
 - a) Neoadjuvant therapy for resectable synchronous liver and/or lung metastasis
 - b) Initial treatment for resectable metachronous metastases; OR
5. Therapy as a single agent for deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] disease only for one of the following:
 - a) Following primary treatment for locally unresectable or medically inoperable disease
 - b) Primary treatment for synchronous abdominal/peritoneal metastases that are non-obstructing, or following local therapy for existing or imminent obstruction
 - c) Synchronous unresectable metastases
 - d) Unresectable metachronous metastases; OR
6. Systemic therapy for appendiceal adenocarcinoma advanced or metastatic disease that is deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] only, as a single agent and if a candidate for immunotherapy ⁶

Esophageal and Esophagogastric Junction Cancers

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

3. No disease progression on prior therapy with a PD-1 or PD-L1; AND
4. Palliative therapy as a single agent for microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) tumors for patients who are not surgical candidates, or have unresectable locally advanced, recurrent, or metastatic disease with Karnofsky performance score $\geq 60\%$ or ECOG performance score ≤ 2 as second-line or subsequent therapy for progressive disease on, or following prior treatment and who have no satisfactory alternative treatment options ⁷

Gastric Cancer

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. No disease progression on prior therapy with a PD-1 or PD-L1; AND
4. Palliative therapy as a single agent for microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) tumors for locoregional disease in patients who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease with Karnofsky performance score $\geq 60\%$ or ECOG performance score ≤ 2 as second-line or subsequent therapy for progressive disease on, or following prior treatment and who have no satisfactory alternative treatment options ⁸

Hepatocellular Carcinoma

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. No disease progression on prior therapy with a PD-1 or PD-L1; AND
4. Subsequent treatment as a single agent for progressive disease in those with microsatellite instability-high (MSI-H) and/or deficient mismatch repair (dMMR) and have no satisfactory alternative treatment options and one of the following:
 - a) Unresectable disease and are not a transplant candidate
 - b) Liver-confined disease and inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease
 - c) Metastatic disease or extensive liver tumor burden ⁹

Occult Primary

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. No disease progression on prior therapy with a PD-1 or PD-L1; AND
4. Single-agent therapy for microsatellite instability-high (MSI-H)/deficient mismatch repair (dMMR) tumors in symptomatic patients with a performance status of (PS) 1-2 or for asymptomatic patients with microsatellite instability-high (MSI-H)/deficient mismatch repair (dMMR) and with a PS of 0 and aggressive recurrent or advanced disease that has progressed on, or following prior treatment and have no satisfactory alternative treatment options for one of the following:

- a) Axillary involvement in those with a prostate or post-prostatectomy
- b) Lung nodules or breast marker-negative pleural effusion
- c) Resectable liver disease
- d) Peritoneal mass or ascites with non-ovarian histology
- e) Retroperitoneal mass of non-germ cell histology
- f) Unresectable liver disease or disseminated metastases ¹⁰

Ovarian, Fallopian Tube and Primary Peritoneal Cancer

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. No disease progression on prior therapy with a PD-1 or PD-L1; AND
4. Single-agent therapy for persistent disease or recurrence, if microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) recurrent or advanced tumors for one of the following:
 - a) As immediate treatment for serially rising CA-125 in patients who previously received chemotherapy
 - b) For progression on primary, maintenance, or recurrence therapy (platinum-resistant disease)
 - c) For stable or persistent disease (if not on maintenance therapy) (platinum-resistant disease)
 - d) For complete remission and relapse <6 months after completing chemotherapy (platinum-resistant disease)
 - e) For radiographic and/or clinical relapse in patients with previous complete remission and relapse ≥ 6 months after completing prior chemotherapy (platinum-sensitive disease); OR
5. Single-agent therapy for borderline epithelial or serous, platinum-sensitive, or platinum-resistant recurrence, if microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) recurrent or advanced tumors ¹¹

Pancreatic Adenocarcinoma

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. No disease progression on prior therapy with a PD-1 or PD-L1; AND
4. Therapy as a single agent (as alternative systemic therapy not previously used) if microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) mutation-positive for one of the following:
 - a) Good performance status (PS) (ECOG 0-1)
 - b) Intermediate PS (ECOG 2)
 - c) Poor PS (ECOG 3-4); OR

Note: The above agent is used for one of the following:

1. Local recurrence in the pancreatic operative bed after resection
2. Recurrent metastatic disease with or without local recurrence after resection
5. Subsequent therapy as a single agent if microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) for locally advanced or metastatic disease, with disease progression, and one of the following:
 - a) Good performance status PS (ECOG 0-1 with good biliary drainage and adequate nutritional intake)
 - b) Intermediate PS (ECOG 2)
 - c) Poor PS (ECOG 3-4) ¹²

Rectal Cancer

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. No disease progression on prior therapy with a PD-1 or PD-L1; AND
4. Single-agent therapy for deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] only for one of the following:
 - a) Neoadjuvant/definitive immunotherapy for T3, Any N; T1-2, N1-2; T4, Any N; or locally unresectable or medically inoperable disease
 - b) Neoadjuvant treatment for resectable synchronous liver and/or lung metastases
 - c) Neoadjuvant treatment for resectable synchronous liver and/or lung metastases with involved clear circumferential resection margin (CRM) by MRI and previously treated with neoadjuvant radiation with or without concurrent chemotherapy
 - d) Initial treatment for resectable metachronous metastases; OR
5. Therapy as a single agent for deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] only if a candidate for immunotherapy for primary therapy for one of the following:
 - a) Synchronous abdominal/peritoneal metastases that are non-obstructing, or following local therapy for existing or imminent obstruction
 - b) Synchronous unresectable metastases
 - c) Potentially resectable or unresectable isolated pelvic/anastomotic recurrence
 - d) Unresectable metachronous metastases ¹³

Small Bowel Adenocarcinoma

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. No disease progression on prior therapy with a PD-1 or PD-L1; AND
4. Initial therapy as a single agent for advanced or metastatic disease that is deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] only, if prior oxaliplatin exposure in the adjuvant setting or a contraindication to oxaliplatin; OR

5. Subsequent therapy as a single agent for advanced or metastatic disease that is deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] only, if no prior oxaliplatin exposure in the adjuvant setting or a contraindication to oxaliplatin ¹⁴

Uterine Neoplasms

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. No disease progression on prior therapy with a PD-1 or PD-L1; AND
4. Adjuvant treatment in combination with carboplatin and paclitaxel with or without external beam radiation therapy (ERBT) and with or without vaginal brachytherapy for surgically staged patients with stage III-IV endometrioid adenocarcinoma; OR
5. In combination with carboplatin and paclitaxel for stage III-IV tumors including serous carcinoma, clear cell carcinoma, undifferentiated/dedifferentiated carcinoma, or carcinosarcoma for the following:
 - a) Primary surgery as additional treatment with or without sequential external beam radiation therapy (ERBT) and with or without vaginal brachytherapy after total hysterectomy/bilateral salpingo-oophorectomy (TH/BSO); OR

Note: This treatment is not suitable for primary surgery as primary treatment with or without sequential ERBT and with or without brachytherapy.

6. Primary treatment in combination with carboplatin and paclitaxel for stage III-IV endometrioid adenocarcinoma for one of the following:
 - a) Preoperatively for patients presenting with abdominal/pelvic-confined disease that is suitable for primary surgery
 - b) With or without external beam radiation therapy (ERBT), stereotactic body radiation therapy, and/or total hysterectomy/bilateral salpingo-oophorectomy (TH/BSO) for distant metastases that are suitable for primary surgery
 - c) With sequential ERBT and with or without brachytherapy for locoregional extrauterine disease that is not suitable for primary surgery
 - d) Distant metastases that are not suitable for primary surgery; OR

Note: For stages IIIA, IIIB, or IIIC1 with measurable disease; stage IIIC1 with carcinosarcoma, clear cell, serous, or mixed histology regardless of the presence of measurable disease; and stage IIIC2 or stage IV regardless of the presence of measurable disease.

7. First-line therapy (or second-line or subsequent therapy) in combination with carboplatin and paclitaxel for recurrent disease for one of the following:
 - a) Isolated metastases
 - b) Disseminated metastases with or without sequential palliative external beam radiation therapy (ERBT)
 - c) With sequential ERBT with or without brachytherapy for locoregional recurrence in patients with no prior radiation therapy (RT) to the site of recurrence, or received previous brachytherapy only

- d) With sequential ERBT for locoregional recurrence in patients with disease confined to the vagina or paravaginal soft tissue, or in pelvic, para-aortic, or common iliac lymph nodes after surgical exploration
 - e) With or without sequential ERBT for locoregional recurrence in patients with upper abdominal or peritoneal disease after surgical exploration
 - f) With or without sequential palliative ERBT or brachytherapy for locoregional recurrence in patients who have received prior ERBT to the site of recurrence; OR
8. First-line therapy after prior platinum-based therapy or second-line or subsequent therapy as a single agent for recurrent microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) disease that has progressed on or following prior treatment with a platinum-containing regimen for one of the following:
- a) For isolated metastases
 - b) For disseminated metastases with or without sequential palliative external beam radiation therapy (ERBT)
 - c) With sequential ERBT with or without brachytherapy for locoregional recurrence in patients with no prior radiation therapy (RT) to the site of recurrence, or who received previous brachytherapy only
 - d) With sequential ERBT for locoregional recurrence in patients with disease confined to the vagina or paravaginal soft tissue, or in pelvic, para-aortic, or common iliac lymph nodes after surgical exploration
 - e) With or without sequential ERBT for locoregional recurrence in patients with upper abdominal or peritoneal disease after surgical exploration
 - f) With or without sequential palliative ERBT or brachytherapy for locoregional recurrence in patients who have received prior ERBT to the site of recurrence

Note:

- 1. Coverage of dostarlimab-gxly will be provided for an FDA-approved indication or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1, 2A, or 2B recommendation or when all criteria are met.
- 2. Individuals receiving PD-1 or PD-L1 therapy should NOT be receiving therapy for an autoimmune disease or chronic condition with a systemic immunosuppressant.

Authorization Period and Renewal Criteria

- 1. Initial Authorization Period: 12 months
- 2. Renewal Criteria: No evidence of disease progression or unacceptable toxicity
- 3. Renewal Authorization Period: 12 months

Dostarlimab-gxly: References

- 1. National Cancer Institute; Dostarlimab-gxly; Updated June 9, 2023.
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3. National Comprehensive Cancer Network Guidelines. Ampullary Adenocarcinoma (Version 1.2023). https://www.nccn.org/professionals/physician_gls/pdf/ampullary.pdf. Accessed June 14, 2023.
4. National Comprehensive Cancer Network Guidelines. Biliary Tract Cancers (Version 2.2023). https://www.nccn.org/professionals/physician_gls/pdf/btc.pdf. Accessed June 14, 2023.
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6. National Comprehensive Cancer Network Guidelines. Colon Cancer (Version 2.2023). https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed June 14, 2023.
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12. National Comprehensive Cancer Network Guidelines. Pancreatic Adenocarcinoma (Version 1.2023). https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf. Accessed June 12, 2023.
13. National Comprehensive Cancer Network Guidelines. Rectal Cancer (Version 3.2023). https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Accessed June 12, 2023.
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15. National Comprehensive Cancer Network Guidelines. Uterine Neoplasms (Version 2.2023). https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed June 16, 2023.
16. National Cancer Institute. Immune Checkpoint Inhibitors; April 7, 2022. <https://www.cancer.gov/about-cancer/treatment/types/immunotherapy/checkpoint-inhibitors>. Accessed May 24, 2023.

17. Emerg Med J 2019: Challenge of Immune-Mediated Adverse Reactions in the Emergency Department;36:369-77.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6582806/pdf/emmermed-2018-208206.pdf>. Accessed May 31, 2023.

Dostarlimab-gxly: Coding (CPT®, ICD 10 and HCPCS) *

*Procedure codes appearing in medical policy documents are only included as a general reference. This list may not be all-inclusive and is subject to updates. In addition, the codes listed are not a guarantee of payment. CPT codes are available through the AMA.

CODE	DESCRIPTION
C15.9	Malignant neoplasm of esophagus, unspecified
C16.9	Malignant neoplasm of stomach, unspecified
C17.9	Malignant neoplasm of small intestine, unspecified
C18.3	Malignant neoplasm of hepatic flexure
C18.9	Malignant neoplasm of colon, unspecified
C20	Malignant neoplasm of rectum
C24.1	Malignant neoplasm of ampulla of Vater
C24.9	Malignant neoplasm of biliary tract, unspecified
C25.9	Malignant neoplasm of pancreas, unspecified
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C55.0	Malignant neoplasm of uterus, part unspecified

C56.9	Malignant neoplasm of unspecified ovary
C80.1	Malignant (primary) neoplasm, unspecified
J9272	Dostarlimab-gxly (Jemperli®)

Dostarlimab-gxly: Revision and Review History

No.	Description	Date(s)
1	Original Effective Date:	1/1/2024
2	Policy Review Dates:	7/20/2023
3	Policy Revision Dates:	
4	Department Owner:	Medical Affairs
5	NH Advisory Committee Approval Dates:	9/20/2023
6	Revision Changes:	