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ONCOLOGY PRODUCTS UPDATED PRIOR AUTHORIZATION CRITERIA

Dear Provider,

Effective March 1, 2024, the criteria for the oncology products listed in Table 1 will be updated. These products are on or will be added to the **non-Medicare** list of office-administered drugs requiring prior authorization. **This letter is a notification of the upcoming change in prior authorization criteria required before administering this medication in a physician's office.**

Table 1. List of Oncology Products that have updated prior authorization criteria:

BRAND NAME	GENERIC NAME	HCPCS
Jemperli	Dostarlimab-gxly	C9082, J9272
Keytruda	Pembrolizumab	J9271
Blincyto	Blinatumomab	J9039
Folotyn	Pralatrexate	J9307

Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington, Options, Inc. requires prior authorization for a select group of injectable drugs that may be administered under the medical benefit in a physician's office or by home infusion. These reviews are intended to ensure consistent benefit adjudication as well as appropriate utilization in accordance with the Kaiser Permanente Pharmacy & Therapeutics Committee's evidence-based criteria for coverage.

Prior Authorization Criteria for Oncology Products (changes are in bold):

DRUG NAME	COVERAGE CRITERIA
BLINATUMOMAB	**Covered for patients with Philadelphia Chromosome positive Acute Lymphoblastic Leukemia Ph(+) ALL:** • **In combination with either ponatinib or dasatinib for patients who are not candidates for intensive chemotherapy.** • **Or as monotherapy for patients who have less than complete response (CR) after first line therapy.**
PRALATREXATE	**Covered for the treatment of patients with Relapsed/Refractory Peripheral T-Cell Lymphoma (R/R PTCL) in the 3rd line setting or beyond.**
DOSTARLIMAB-GXLY	Covered for the treatment of patients with locally advanced rectal cancer who are dMMR. • **Limit to 9 cycles**
PEMBROLIZUMAB	Covered for:

DRUG NAME	COVERAGE CRITERIA
	1. Treatment of patients with metastatic urothelial carcinoma who are platinum ineligible as first line therapy or second line therapy after platinum therapy 2. Treatment of patients with melanoma: • Covered for treatment of patients with unresectable or metastatic melanoma as a single agent o Covered in combination with CTLA-4 o Not covered as monotherapy following progression on checkpoint inhibitor. • Covered for adjuvant treatment of resected stage IIB, IIC melanoma. • Covered for neoadjuvant treatment of Stage IIIB-IV 3. Treatment of patients with non-small cell lung cancer (NSCLC): • Covered as single agent for patients with metastatic disease: o Patients without EGFR or ALK driver mutations who have not previously undergone systemic therapy for metastatic disease. o Patients who have not previously undergone systemic therapy for metastatic disease without EGFR or ALK driver mutations. o Patients with ROS-1 gene aberrations must have progressed on approved applicable agents (e.g., ceritinib, alectinib, lorlatinib, entrectinib) and have not previously progressed on with PD-1 immunotherapy agents. o Who have progressed on or after platinum-based chemotherapy, tumor must demonstrate ≥ 1% expression of PD-L1 via the companion IHC diagnostic and have not previously progressed on PD-1 immunotherapy agents. • Covered in combination with pemetrexed and cisplatin or carboplatin for patients with metastatic non-squamous NSCLC: o Patients who have not previously undergone systemic therapy for metastatic disease without EGFR or ALK driver mutations. o Patients with ROS-1 gene aberrations must have progressed on approved applicable agents (e.g., ceritinib, alectinib, lorlatinib, entrectinib) and have not previously progressed on PD-1 immunotherapy agents. • Covered in combination with carboplatin and paclitaxel for patients with metastatic squamous NSCLC: o Patients who have not previously undergone systemic therapy for metastatic disease. 4. Treatment of metastatic pancreatic adenocarcinoma: • Covered as second line therapy if MSI-H or dMMR tumor status. • Covered as third line therapy if TMB is at least 10. 5. Treatment of hepatocellular carcinoma if ALL the following apply: • Second line treatment option • Child Pugh A • Immunotherapy Naïve 6. Treatment of neoadjuvant triple negative breast cancer in patients with high-risk disease (High Tumor Burden or ≥T1c and LN + or ≥T2) when combined with paclitaxel, carboplatin or doxorubicin and cytoxan.

DRUG NAME	COVERAGE CRITERIA
	7. Adjuvant treatment of TNBC after neoadjuvant pembrolizumab treatment. • Maximum of 1 year (9 cycles) of treatment including neoadjuvant cycles 8. First line therapy for metastatic, unresectable, or recurrent PDL1 (CPS ≥10) positive, triple negative breast cancer, or after 1st line therapy if no prior immunotherapy in the following conditions: • ER/PR negative and HER2 Low in the first line setting OR • In combination with carboplatin and gemcitabine OR • In combination with paclitaxel 9. Treatment of stage 3 and 4 or recurrent endometrial cancer after first line: • As monotherapy if microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden (TMB) high • In combination with lenvatinib if microsatellite instability stable (MSS/pMMR) 10. Locally advanced or metastatic Basal Cell carcinoma • If not amenable to RT or surgery as first line therapy. • If used as second line therapy. 11. Treatment of metastatic or advanced GEJ, esophageal, gastric cancer: • In the first line setting: o as monotherapy o OR in combination with platinum-based chemotherapy • In the second line setting: o if immunotherapy naïve o PD-L1 greater or equal to 1 or dMMR/MSI-H • In the 3rd line setting and beyond if TMB high (greater or equal to 10 mut/MB) 12. Treatment of metastatic esophageal squamous cell carcinoma: • In the first line setting if combined with platinum-based chemotherapy • As monotherapy if ALL of the following are met: o Immunotherapy naïve o Progression following platinum-based chemotherapy 13. Treatment of Nasopharyngeal Metastatic, recurrent, or unresectable squamous-cell carcinoma of the head and neck. • As first line treatment if combined with chemotherapy, up to 24 months. • As second line treatment for up to 24 months. • In patients who are MSI-H or TMB-H • Not covered for failure or progression on or after an alternative PD-L1 agent. 14. Treatment of Unresectable or Metastatic Biliary Tract Cancer if MSI-H /dMMR or TMB greater or equal to 10. 15. Relapsed/Refractory classical Hodgkin Lymphoma (cHL) after at least one prior line of therapy and no prior I/O therapy. 16. Treatment of patients with metastatic or unresectable squamous-cell carcinoma of the head and neck (SCCHN): • Covered as first line a single agent if CPS ≥1.

DRUG NAME	COVERAGE CRITERIA
	○ in combination with platinum chemotherapy for first line treatment (regardless of CPS). • Not covered for failure or progression on or after an alternative PD-L1 agent 17. Treatment of mesothelioma after first line therapy for patients who are immunotherapy naïve 18. Treatment of stage IV Colorectal Cancer that is • Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) OR • Non-oligometastatic for second-line or greater therapy with tumor mutational burden (TMB) ≥10 • Note: If progression noted off immuno-oncology (IO) therapy after completion of 2 years of therapy, may restart utilizing first line IO therapy options. 19. Treatment of renal cell carcinoma (RCC): • In combination with axitinib for patients with metastatic renal clear cell carcinoma (RCC) who are not surgical candidates OR • As adjuvant therapy if given as monotherapy for up to one year 20. Treatment of patients with metastatic, or locally advanced, cutaneous squamous cell carcinoma 21. Covered for the treatment of metastatic castration resistant prostate cancer if: • MSI-H, dMMR • TMB at least 10 mut/Mb 22. Covered for the treatment of patients with metastatic perianal/anal cancer: • Following platinum-based therapy if no prior immunotherapy used AND: ○ No molecular findings to guide treatment OR ○ MSI-H/dMMR or TMB-H (greater or equal to 10 mut/MB) 23. Covered for the treatment of patients with Salivary Gland Cancer if all the following apply: • Adenocarcinomas NOS, Mucoepidermoid or Salivary Duct Carcinoma • Recurrent Metastatic disease • Not a candidate for surgery or radiation • TMB greater or equal to 10 Mutations/Mb 24. Covered for patients with Anaplastic Thyroid Carcinoma (ATC) if no actionable mutation present or as subsequent line of therapy AND in combination with Lenvatinib. • Patient must be intolerant or contraindicated to chemotherapy. Note: Must be administered in a non-hospital setting when used as monotherapy (new starts and maintenance monotherapy). Dose exceptions for new starts: 2 doses within 3 months. See site of care policy for criteria, reauthorization, and exceptions for new starts. **Pembrolizumab authorizations for all indications, will be limited to 1 year with re-authorization ONE additional year for patients with stable disease.**

DRUG NAME	COVERAGE CRITERIA
	Site of Care Policy URL *https://wa-provider.kaiserpermanente.org/static/pdf/provider/clinical-review/infusion-site-care-policy.pdf*

Additional Information

A complete list of office-administered injectable drugs requiring prior authorization can be found on the Kaiser Permanente provider website at https://wa-provider.kaiserpermanente.org/provider-manual/clinical-review/officeinject.

To request prior authorization review, please use the Referral Request online form located on the Kaiser Permanente provider website at https://wa-provider.kaiserpermanente.org/provider-manual/clinical-review/preservice. You can also fax your request to the Review Services department toll-free at 1-888-282-2685.

Thank you for the care you provide to our members, your patients. If you have any questions about this process, please call Review Services at 1-800-289-1363, Monday through Friday from 8 a.m. to 5 p.m.

Sincerely,

Gurpreet Rawat, MD, Chair
Pharmacy & Therapeutics Committee