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ONCOLOGY PRODUCTS UPDATED PRIOR AUTHORIZATION CRITERIA

Dear Provider,

Effective March 1, 2025, the criteria for oncology products in Table 1 and Table 2 will be updated. These products are on the **non-Medicare** list of office-administered drugs requiring prior authorization. **This letter is a notification of the upcoming changes in coverage for these medications under the medical benefit.**

Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington, Options, Inc. (Kaiser Permanente) require 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.

Table 1. List of oncology products that will have coverage restriction

BRAND NAME	GENERIC NAME	HCPCS
Rolvedon	Eflapegrastim	J1449
Udenyca Onbody	Pegfilgrastim-cbqv	Q5111

Table 2. List of oncology products that have updated quantity limits

BRAND NAME	GENERIC NAME	HCPCS
Libtayo	Cemiplimab	J9119
Enhertu	Fam-trastuzumab deruxtecan	J9358
Kadcyla	Ado-trastuzumab emtansine	J9354
Keytruda	Pembrolizumab	J9271

Coverage restriction criteria for oncology products (changes are in bold):

DRUG NAME	COVERAGE CRITERIA
Eflapegrastim (Rolvedon)	~~**Medical necessity review required.**~~ **Not covered, not medically necessary.**
Pegfilgrastim-cbqv (Udenyca Onbody)	~~**Medical necessity review required.**~~ **Not covered, not medically necessary.**

Quantity limit updates for oncology products (changes are in bold):

DRUG NAME	COVERAGE CRITERIA
Cemiplimab (Libtayo)	1. Covered for treatment of patients with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC).

DRUG NAME	COVERAGE CRITERIA
	2. Covered for the treatment of patients with locally advanced cutaneous squamous cell carcinoma. 3. Treatment of metastatic NSCLC if ALL of the following apply: • Without progression on immunotherapy. • PD-L1 positive • No EGFR/ALK mutations. • As a single agent if PS>2 • 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 **Quantity Limit: Approved for a maximum of 4.5 mg/kg, up to 350 mg every 21 days for up to 24 months.**
Fam-trastuzumab deruxtecan (Enhertu)	1. 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 • HER2 positive and AR negative 2. Covered for the treatment of metastatic perianal/anal cancer in the second line setting or beyond if HER2 IHC3+ 3. Covered for the treatment of metastatic pancreatic adenocarcinoma in the third line setting or beyond if HER2 IHC3+ 4. Covered for recurrent, unresectable or metastatic HER2 positive (IHC3+ or IHC2 and ISH +) breast cancer after disease progression on initial HER 2 directed therapy (i.e., trastuzumab [e.g., Kanjinti], pertuzumab, TDM-1), OR with documented progression/recurrence within 12 months after completion of neo-adjuvant therapy or adjuvant therapy. 5. HER2 low recurrent, unresectable or metastatic breast cancer defined as IHC1+ or IHC2+ and ISH Negative: Covered if the following conditions (when applicable) are met: • If HR positive: Refractory to CDK 4/6 inhibition: o < 12 months CDK4/6 duration and ESR1 positive, must show progression or intolerance to everolimus with tamoxifen or fulvestrant. (if not previously used) OR o ≥ 12 months duration on CDK4/6 inhibition and ESR1 positive must show intolerance or progression on elacestrant. AND o If PIK3CA, AKT1 or PTEN alteration positive: With progression or intolerance with capivasertib or alpelisib AND o If BRCA1/2 positive treatment till progression with a PARPi (Olaparib) • If HR negative with PD-L1 positive (CPS ≥ 10): Previous therapy with pembrolizumab plus chemotherapy, until toxicity,

DRUG NAME	COVERAGE CRITERIA
	progression or duration of 2 years. AND If BRCA 1/2 positive, previous therapy with a PARP inhibitor until intolerable toxicity or progression. AND Previous taxane followed by sacituzumab govitecan-hziy until toxicity or progression. OR • If HR negative with PD-L1 negative (CPS < 10) or unknown: Previous therapy with a PARP inhibitor (if BRCA 1/2 mutated) until intolerable toxicity or progression. AND Previous taxane followed by sacituzumab govitecan-hziy until toxicity or progression. 6. Covered for the treatment of HER-2 positive metastatic or advanced GEJ, esophageal, gastric cancer in the second line setting after previous treatment with trastuzumab (e.g., Kanjinti) 7. Covered for the treatment of patients with HER2 (ErbB2), NSCLC after initial treatment with chemotherapy +/- immunotherapy as detected by NGS. 8. Covered for the treatment of stage IV Colorectal Cancer in the third line setting if all the following apply: • HER 2 amplification 9. Covered for the treatment of Stage B/C hepatocellular carcinoma in the third line setting if: • HER2 Positive • Child Pugh A **Quantity Limit: Fam-trastuzumab deruxtecan-nxki authorizations for all breast cancer indications, will be limited to a maximum dose of 5.4 mg/kg every 21 days for 1 year. Requests for continuation of therapy will require documentation of disease stability (lack of progression)**
Ado-trastuzumab emtansine (Kadcyla)	1. Covered for use as a single agent in patients with a documented diagnosis of recurrent, unresectable, or metastatic HER2+ breast cancer who: • Have received prior therapy for advanced disease including a trial and failure of at least one trastuzumab + taxane-containing chemotherapy regimen. 2. Covered for use as adjuvant therapy in patients with a documented diagnosis of HER2-positive early breast cancer who: • Have residual invasive disease in the breast or axilla at surgery after receiving neoadjuvant therapy containing a taxane and trastuzumab (e.g., Kanjinti) 3. 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 • HER2 positive AND o AR negative as first line. o AR positive as second line.

DRUG NAME	COVERAGE CRITERIA
	Quantity Limit: Ado-trastuzumab emtansine authorizations for all breast cancer indications, will be limited to a maximum dose of 3.6 mg/kg every 21 days for 1 year. Requests for continuation of therapy will require documentation of disease stability (lack of progression)
Pembrolizumab (Keytruda)	1. Treatment of patients with metastatic urothelial carcinoma • As first line therapy if combined with enfortumab or • Second line monotherapy after platinum-based 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 stage II-III non-small cell lung cancer (NSCLC), ALL of the following must apply: • Candidate for neoadjuvant therapy. • If EGFR/ALK negative. • Combined with platinum-based chemotherapy 4. Treatment of stage IV Thymic Carcinoma as subsequent therapy after chemotherapy. 5. 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. 6. Treatment of hepatocellular carcinoma if ALL the following apply: • Second line treatment option • Child Pugh A • Immunotherapy Naïve 7. 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. 8. Adjuvant treatment of TNBC after neoadjuvant pembrolizumab treatment. 9. 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 10. Treatment of Endometrial Cancer if:

DRUG NAME	COVERAGE CRITERIA

	• First Line (systemic treatment naïve)
	  ○ dMMR/MSI-H & Stage III disease.
	  ○ Stage IV
	• Recurrent Endometrial Cancer
	  ○ Platinum free interval > 6months or No prior systemic treatment.
	  ○ Platinum free interval ≤ 6months, dMMR/MSI-H, or pMMR/MSS if combined with Lenvatinib.
	11. Treatment of locally advanced, recurrent or metastatic cervical cancer when ALL of the following apply:
	• Not a surgical candidate
	• PDL1 Positive (CPS ≥ 1)
	• Immunotherapy naïve
	12. For patients with locoregionally advanced colorectal cancer as neoadjuvant treatment if:
	• Microsatellite instability-high (MSIH) or mismatch repair deficient (dMMR)
	• Patients who are immunotherapy naïve
	13. Locally advanced or metastatic Basal Cell carcinoma
	• If not amenable to RT or surgery as first line therapy.
	• If used as second line therapy.
	14. Treatment of metastatic or advanced GEJ, esophageal, gastric cancer:
	• In the first line setting:
	  ○ as monotherapy
	  ○ OR in combination with platinum-based chemotherapy
	  ○ OR in combination with trastuzumab for Her2 over expression and with CPS greater or equal to 1.
	• In the second line setting:
	  ○ if immunotherapy naïve
	  ○ 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)
	15. 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:
	  ○ Immunotherapy naïve
	  ○ Progression following platinum-based chemotherapy
	16. Treatment of metastatic, recurrent, or unresectable squamous-cell carcinoma of the head and neck.
	• As first line treatment
	• As second line or subsequent treatment of solid tumors.
	• In patients who are MSI-H or TMB-H

DRUG NAME	COVERAGE CRITERIA
	• Not covered for failure or progression on or after an alternative PD-L1 agent. 17. Treatment of Unresectable or Metastatic Biliary Tract Cancer: • In the first line setting if combined with Cisplatin and gemcitabine. • In the second line setting, as monotherapy if MSI-H /dMMR AND if patient is pembrolizumab naïve. • In the third line setting if TMB- High (greater or equal to 10mut/MB) AND patient is pembrolizumab naïve. 18. Treatment of metastatic Merkel cell carcinoma. 19. Relapsed/Refractory classical Hodgkin Lymphoma (cHL) after at least one prior line of therapy and no prior I/O therapy. 20. 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. o 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 21. Treatment of mesothelioma after first line therapy for patients who are immunotherapy naïve 22. 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. 23. Treatment of renal cell carcinoma (RCC): • In combination with axitinib or Lenvatinib for patients with metastatic renal clear cell carcinoma (RCC) who are not surgical candidates OR • As adjuvant therapy if intermediate or high-risk disease, when given as monotherapy for up to one year 24. Covered for the treatment of metastatic castration resistant prostate cancer if: • MSI-H, dMMR • TMB at least 10 mut/Mb 25. Covered for the treatment of patients with metastatic perianal/anal cancer: • Following platinum-based therapy if no prior immunotherapy used AND: o No molecular findings to guide treatment OR

DRUG NAME	COVERAGE CRITERIA
	○ MSI-H/dMMR or TMB-H (greater or equal to 10 mut/MB) 26. 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 27. 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. Quantity Limit: Pembrolizumab authorizations for all indications, will be limited to 1 year. Requests for an additional year of therapy will require documentation of disease stability (lack of progression). **Quantity Limit (applies to all indications): Max dose 200 mg every 3 weeks or 400 mg every 6 weeks.**

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 (login required) 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,

Ravi Ubriani, MD, Chair
Pharmacy & Therapeutics Committee