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ONCOLOGY PRODUCTS UPDATED PRIOR AUTHORIZATION CRITERIA

Dear Provider,

Effective September 1, 2025, the criteria for the oncology products in Table 1 will be updated to include quantity limits. 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 have prior authorization criteria:

BRAND NAME	GENERIC NAME	HCPCS
Empaveli	Pegcetacoplan	J3490, J3590
Imfinzi	Durvalumab	J9173
Imjudo	Tremelimumab-actl	C9147, J9347
Opdivo	Nivolumab	J9299

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

DRUG NAME	COVERAGE CRITERIA
PEGCETACOPLAN	Covered for adult patients with paroxysmal nocturnal hemoglobinuria (PNH) who meet all of the following: • Diagnoses confirmed by high-sensitivity flow cytometry and established by or in consultation with a hematology specialist. • Patient meets one of the following: o Transfusion-dependent** -OR- o History of major adverse vascular event from thromboembolism. • One of the following clinical conditions: o Patient has a known allergy of intolerance of preferred agents ravulizumab and eculizumab -OR- o Patient has a lack of response to ravulizumab and eculizumab, defined as hemoglobin < 10.5 g/dL and continued need for transfusions after 3 months of treatment. • Initial authorization: 6 months

DRUG NAME	COVERAGE CRITERIA
	• Reauthorization: reassessment every 12 months to confirm clinical benefit, including disease stability or improvement in symptoms. **Transfusion-dependence defined as hemoglobin less than 7 g/dL OR hemoglobin less than or equal to 9 g/dL, and patients is experiencing symptoms from anemia requiring transfusion. **Quantity Limit: 1,080 mg twice weekly**
DURVALUMAB	Biliary Tract Cancer: • Covered for the treatment of Unresectable or Metastatic Biliary Tract Cancer in the first line setting, if combined with Cisplatin and Gemcitabine, AND contraindicated or intolerant to Pembrolizumab. • **Max therapy of 2 years.**
TREMELIMUMAB-ACTL	Hepatocellular (HCC): Covered as first-line treatment of advanced (Stage B/C) Hepatocellular Carcinoma (HCC) If ALL the following apply: • Child Pugh A • Used in combination with Durvalumab. • Not a candidate for bevacizumab (i.e., bleeding risk or pending surgery) • Immunotherapy naïve **Quantity Limit: Covered for up to 2 years**
NIVOLUMAB	Colorectal Cancer: 1. Treatment of stage IV colorectal cancer that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • Patients who are immunotherapy naïve • Combined with ipilimumab • Note: If progression noted off immuno-oncology (IO) therapy after completion of 2 years of therapy, may restart utilizing first-line IO therapy options. 2. 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 • Combined with ipilimumab. • Limited to one-year total therapy. Urothelial Carcinoma: 3. Treatment of patients with metastatic urothelial carcinoma as second-line therapy after platinum-based therapy Bladder Cancer: 4. Covered for the treatment of muscle invasive bladder cancer with staging T2T4, N0-N1 as adjuvant therapy in patients who have progressed on cisplatin or who are cisplatin ineligible (CrCl ≥40 mL/min (24-hour urine clearance, or at least grade 2 Neuropathy, hearing loss, or ECOG PS. Esophageal Squamous Cell Carcinoma:

DRUG NAME	COVERAGE CRITERIA
	5. Treatment of metastatic esophageal squamous cell carcinoma as monotherapy if ALL the following apply: • Immunotherapy naïve • Progression following platinum-based chemotherapy Squamous Cell Head and Neck: 6. Treatment of metastatic, recurrent, or unresectable squamous-cell carcinoma of the head and neck. • Not covered for failure or progression on or after an alternative PD-L1 agent. Hodgkin Lymphoma: 7. Treatment of patients with Hodgkin lymphoma: • Diagnosis of relapsed or refractory Hodgkin Lymphoma AND • Progression of disease on or after one or more lines of therapy and no prior I/O therapy. 8. Treatment of patients with Stage III/IV Hodgkin Lymphoma: • In the first line setting as combined therapy Primary Central Nervous System Lymphoma (PCNSL) 9. Treatment of primary central nervous system lymphoma (PCNSL) after first progression or lack of response to first-line therapeutic options. Melanoma 10. Treatment of patients with melanoma: • Covered for unresectable or metastatic disease for up to 2 years, either: o As monotherapy, except following progression on an alternative PD-1 agent such as pembrolizumab. o In combination with CTLA-4 agents such as ipilimumab in patients with an ECOG score of 0 or 1 • Covered for adjuvant treatment of resected stage IIIB-IIC disease for up to 1 year. • Covered for neoadjuvant treatment of stage III Melanoma if all of the following apply: o One or more Lymph nodes AND o 3 or less in-transit metastasis AND o Combined with Ipilimumab o Followed by Nivolumab for adjuvant treatment if greater than 10% viable tumor. Uveal melanoma 11. Treatment of patients with uveal melanoma: • For widely metastatic disease, o If combined with ipilimumab AND o If patient is tebentafusp ineligible. Mesothelioma 12. Covered for locally advanced unresectable mesothelioma Non-small cell lung cancer (NSCLC): 13. Treatment of patients with advanced-stage non-small cell lung cancer (NSCLC) if:

DRUG NAME	COVERAGE CRITERIA
	• Covered as single agent for patients who have progressed on or after chemotherapy, have no EGFR or ALK mutations, and have not previously been treated with PD-1 immunotherapy agents. • Patients with ROS-1 gene aberrations must have progressed on approved applicable agents. • In combination with ipilimumab for patients with PD-L1 expression who have not previously been treated with PD-1 immunotherapy agents. 14. 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. Small cell lung cancer (SCLC): 15. Treatment of small cell lung cancer (SCLC): • Covered as subsequent therapy if PS 0-2, relapse less than 6 months, and have not previously been treated with PD-1 immunotherapy agents Metastatic nonpapillary renal cell carcinoma (RCC) 16. Treatment of patients with metastatic nonpapillary renal cell carcinoma (RCC) if combined with either ipilimumab OR cabozantinib OR as monotherapy if used in the second line setting and patient is immunotherapy naïve. Nasopharyngeal squamous-cell carcinoma of the head and neck (SCCHN): 17. Treatment of patients with recurrent or metastatic non-nasopharyngeal squamous-cell carcinoma of the head and neck (SCCHN): • If not eligible for chemotherapy • Not covered for patients who progressed on or after an alternative PD-1 agent. GEJ, Esophageal, Gastric Cancer 18. Treatment of metastatic GEJ, esophageal, gastric cancer in the first line setting 19. Covered for locally advanced esophageal, GEJ, or gastric cancer after neoadjuvant chemotherapy with residual disease at surgery. Coverage not to exceed 1 year. 20. Treatment of Siewert type I and II Esophageal, GEJ for up to 1 year in patients who received neoadjuvant chemoradiation and have residual disease at surgery. 21. Covered as adjuvant therapy for patients with completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease, who have received neoadjuvant chemoradiotherapy for a total treatment duration of one year. 23. Covered as combination therapy as first-line treatment of Esophageal Squamous cell Metastatic Carcinoma.

DRUG NAME	COVERAGE CRITERIA
	23. Covered as peri-operative/neoadjuvant treatment of Gastric Cancer/GEJ Siewert III: • If planned Lymphadenectomy AND • If combined with Ipilimumab AND • dMMR/MSI-H tumor 24. Treatment of metastatic esophageal squamous cell carcinoma: • In the first line setting, if combined with platinum-based chemotherapy or ipilimumab and Immunotherapy naïve Hepatocellular carcinoma (HCC): 25. Covered for the treatment of Hepatocellular Carcinoma if ALL the following apply: • Second-line treatment option if combined with ipilimumab • Child Pugh A • Immunotherapy naïve Merkel cell carcinoma: 26. Neo-adjuvant treatment of non-metastatic Merkel cell carcinoma. Note: Must be administered in a non-hospital setting. See site of care policy* for criteria, reauthorization, and exceptions for new starts. *Applies to drug unless administered in combination with another provider-administered chemotherapy for which site of care restriction does not apply (i.e., concurrent oral chemotherapy is not an indication to waive site of care). **Quantity Limit: Nivolumab 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).**

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. 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