KAISER PERMANENTE®

206-988-2000
206-988-2001
prnotification@kp.org

Kaiser Foundation Health Plan of Washington
Kaiser Foundation Health Plan of Washington Options, Inc.
CONTRACT MANAGER NAME
Provider Communications, RCB-C2W-02
PO Box 34262, Seattle WA 98124-1262

MARCH 26, 2021

SITE OF CARE PRIOR AUTHORIZATION REQUIREMENT FOR PEMBROLIZUMAB (KEYTRUDA) AND NIVOLUMAB (OPDIVO)

Dear Provider,

Effective June 1, 2021, Site of Care prior authorization criteria will apply to the medications noted in Table 1 below. Site of Care is a prior authorization for the location at which an infused medication is administered under the medical benefit. When Site of Care is applied to a medication, the following site of care types are acceptable: an **outpatient standalone clinic, infusion center, provider's office, or home infusion**. Outpatient hospital-based infusion sites are not approved sites. This letter is notification that prior authorization approval is required before administering this medication under the medical benefit.

This only applies to Kaiser Foundation Health Plan of Washington Health Maintenance Organization (HMO) members and Kaiser Foundation Health Plan of Washington Options, Inc. Point of Service (POS) and Preferred Provider Organization (PPO) members who are ≥ 13 years old. **This change will NOT affect Medicare Advantage members.**

The following injectable drug will be added to the list of drugs requiring prior authorization for Site of Care:

Drug Table 1. Additional Drugs Requiring Site of Care Prior Authorization

Therapy Class/Indication	Name	Generic Name	HCPCS
Chemotherapy, when used as maintenance, monotherapy (does not apply to combination chemotherapy regimens)	KEYTRUDA	Pembrolizumab	C9027 J9271
Chemotherapy, when used as maintenance, monotherapy (does not apply to combination chemotherapy regimens)	OPDIVO	Nivolumab	J9299

Prior authorization clinical criteria were previously established for Pembrolizumab (Keytruda) J9271 and Nivolumab (Opdivo) J9299. Members who are initiating treatment with Pembrolizumab (Keytruda) or Nivolumab (Opdivo) will require a prior authorization review based upon the clinical criteria **and** the Site of Care.

Prior Authorization Criteria for Pembrolizumab (Keytruda) and Nivolumab (Opdivo):

DRUG NAME	COVERAGE CRITERIA
PEMBROLIZUMAB	Treatment of patients with advanced stage urothelial carcinoma: • Patient must have disease progression during or following platinum-based chemotherapy OR

DRUG NAME	COVERAGE CRITERIA

	• Patient must have disease progression within 12 months of neoadjuvant or adjuvant platinum-based chemotherapy OR
	• Patient must be cisplatin ineligible (defined as meeting one of the following criteria):
	  o ECOG performance status of ≥2
	  o Creatinine clearance 30-60 mL/min o Grade ≥2 audiometric hearing loss
	  o Grade ≥2 peripheral neuropathy
	  o New York Heart Association Class III or IV heart failure
	
	Treatment of patients with melanoma:
	• Covered for treatment of patients with unresectable or metastatic melanoma as a single agent at 2 mg/kg every 3 weeks:
	  o Combination with CTLA-4 not covered
	  o Not covered following progression on nivolumab
	• Covered for adjuvant treatment of resected stage III melanoma
	
	Treatment of patients with NSCLC:
	• Covered as single agent for patients with 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
	
	Treatment of metastatic pancreatic adenocarcinoma:
	• Covered as second line therapy if MSI-H or dMMR tumor status
	
	Not covered, not medically necessary for treatment of advanced endometrial carcinoma including disease that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)
	
	Treatment of patients with metastatic or unresectable non-nasopharyngeal squamous-cell carcinoma of the head and neck (SCCHN):
	  • Covered as a single agent if CPS ≥1 or in combination with platinum chemotherapy for first line treatment
	  • Covered for patients who progressed platinum-based chemotherapy

DRUG NAME	COVERAGE CRITERIA
	• Not covered for failure or progression on or after an alternative PD-L1 agent Covered for treatment of stage IV Colorectal Cancer that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) and is RAS/BRAF wild type Covered in combination with axitinib for patients with metastatic renal clear cell carcinoma who are not surgical candidates
NIVOLUMAB	Treatment of patients with metastatic colorectal cancer: Patients must meet all the following • Diagnosis of metastatic or recurrent colorectal cancer • Documentation that the tumor is MSI-H or dMMR by immunohistochemistry or polymerase change reaction (PCR) testing • Disease progression on or after treatment with or contraindication to fluoropyrimidine, oxaliplatin, and irinotecan • Nivolumab will be used as monotherapy • No prior therapy with a PD-1 or programmed death-ligand 1 (PD-L1) blocking antibody therapy Treatment of patients with classical Hodgkin Lymphoma: Patient must meet all the following • Diagnosis of relapsed or refractory classical Hodgkin Lymphoma AND • Progression of disease on or after three or more lines of therapy that includes an HDT/ASCT and brentuximab vedotin OR • After HDT/ASCT and post-transplant brentuximab vedotin 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 ECOG score of 0 or 1 and have not progressed on a CTLA-4 agent such as ipilimumab or a PD-1 agent such as nivolumab or pembrolizumab • Covered for adjuvant treatment of resected stage III disease for up to 1 year Treatment of patients with advanced stage NSCLC: • 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 been previously been treated with PD-1 immunotherapy agents Treatment of patients with renal cell carcinoma (RCC): • Covered for advanced (metastatic or unresectable) renal cell carcinoma (RCC) after failure of at least one antiangiogenic agent (e.g., sunitinib, pazopanib)

DRUG NAME	COVERAGE CRITERIA
	• Covered in combination with ipilimumab for previously untreated advanced clear-cell renal cell carcinoma categorized as intermediate or poor risk Treatment of patients with recurrent or metastatic non-nasopharyngeal squamous-cell carcinoma of the head and neck (SCCHN): • Covered as single agent for patients who have progressed on or after platinum-based chemotherapy • Not covered for patients who progressed on or after an alternative PD-1 agent 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 Not covered, not medically necessary for advanced hepatocellular carcinoma due to limited evidence

You can request authorization using one of the following methods:

- Use the Kaiser Permanente provider website. You can send your request for authorization using our Referral Request tool. Using this method is easy and is the quickest way to obtain your authorization, sometimes immediately if your request is auto-approved.
- Fax your request to the Review Services department at 1-888-282-2685.
- Contact Review Services at 1-800-289-1363, Monday – Friday from 8 a.m. to 5 p.m. After business hours, please leave a voice message with your contact information. Messages received after normal business hours are returned on the next business day.

A complete list of office-administered injectable drugs requiring prior authorization can be found on Kaiser Permanente provider website at https://wa-provider.kaiserpermanente.org under the header "Authorization & Clinical Review." Site of Care reviews are intended to ensure consistent benefit adjudication as well as appropriate utilization in accordance with the Medical Policy Committee's criteria for coverage.

Site of Care Prior Authorization Criteria Exceptions:

A hospital outpatient setting may be used for infusion of drugs on the site of care optimization list only if **one** of the following is met:

1. Member is medically unstable based upon submitted clinical history. Examples, including, but not limited to, cardiopulmonary conditions that may increase risk of adverse reactions, inability to safely tolerate intravenous volume loads, unstable vascular access requiring ultrasound guidance; or
2. Previous experience of a severe adverse event following infusion (examples, including, but not limited to, anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure); or
3. Continuing experience of adverse events that cannot be mitigated (e.g. not mitigated by pre-medications or by reducing the rate of infusion); or
4. Physically and/or cognitively impaired AND no home caregiver available; or
5. The member's home is not eligible for home infusion services (such as home is not within the service area determined by the home infusion provider or is deemed unsuitable for care by the home infusion provider). Clinical notes supporting an exception must be included (e.g., dates of prior anaphylactic experience, specific details of adverse reactions and attempts to mitigate).

Note: For new start members, alternative Site of Care criteria will be waived for payment of the administration of the first dose for all drugs, to allow for adequate transition time to arrange for a non-

hospital outpatient setting for the infusion. Further dose exceptions may be applicable depending on the drug (see Table 1) and/or to ensure continuity of care.

Additional Information

Coverage determinations, once completed, will be available online using the Referral Status Inquiry application and will be mailed to the member.

Failure to obtain a prior authorization for the above medications will result in a denial of payment.

Please refer to the provisions of your agreement with Kaiser Permanente, including obtaining the member's prior written agreement to be financially responsible for the specific non-covered service, to determine when providers may bill a member for non-covered services.

If you have any questions about these changes, please contact the Provider Assistance Unit toll-free at 509-241-7206 or toll-free at 1-888-767-4670, Monday – Friday from 8 a.m. to 5 p.m.

Sincerely,

Peter Barkett, MD, Chair
Pharmacy & Therapeutics Committee