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January 15, 2025

SITE OF CARE PRIOR AUTHORIZATION REQUIREMENT FOR ONCOLOGY MEDICATIONS

Dear Provider,

Effective April 1, 2025, Site of Care prior authorization criteria will apply to the medications noted in Table 1 and Table 2 below. These products are on the **non-Medicare** list of office-administered drugs requiring prior authorization. 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 stand-alone clinic, infusion center, provider's office, or home infusion**. Outpatient hospital-based infusion sites are not approved sites. This letter is a notification that prior authorization is required before administering this medication under the medical benefit.

This requirement 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. Drugs Requiring Site of Care Prior Authorization

Therapy Class/Indication	Brand Name	Generic Name	HCPCS
ONCOLOGY	ENHERTU	FAM-TRASTUZUMAB DERXTECAN	J9358
ONCOLOGY	KADCYLA	ADO-TRASTUZUMAB EMTANSINE	J9354

Drug Table 2. Drugs with modified Site of Care Prior Authorization

Therapy Class/Indication	Brand Name	Generic Name	HCPCS
ONCOLOGY	KEYTRUDA*	PEMBROLIZUMAB	J9271, C9027
ONCOLOGY	HERCEPTIN*	TRASTUZUMAB	J9355
ONCOLOGY	KANJINTI*	TRASTUZUMAB-ANNS	Q5117
ONCOLOGY	OGIVRI*	TRASTUZUMAB-DKST	Q5114
ONCOLOGY	ONTRUZANT*	TRASTUZUMAB-DTTB	Q5112
ONCOLOGY	HERZUMA*	TRASTUZUMAB-PKRB	Q5113
ONCOLOGY	TRAZIMERA*	TRASTUZUMAB-QYYP	Q5116
ONCOLOGY	PERJETA*	PERTUZUMAB	J9306, C9292
ONCOLOGY	VELCADE*	BORTEZOMIB	J9041, J9044, J9046, J9048, J9049, J9051
ONCOLOGY	AVASTIN*	BEVACIZUMAB	J9035
ONCOLOGY	MVASI*	BEVACIZUMAB-AWWB	Q5107
ONCOLOGY	ZIRABEV*	BEVACIZUMAB-BVZR	Q5118

ONCOLOGY	ALYMSYS*	BEVACIZUMAB-MALY	C9142, Q5126
ONCOLOGY	XGEVA*	DENOSUMAB	J0897
ONCOLOGY	OPDIVO*	NIVOLUMAB	J9299

Prior authorization clinical criteria were previously established for these oncology medications. Members initiating treatment with these medications will require a prior authorization review based upon the clinical criteria **and** the Site of Care.

Prior Authorization Site of Care Criteria for Oncology Medications (does not include additional clinical criteria) (changes are in bold):

*The site of care policy can be found on the Kaiser Permanente provider website at https://wa-provider.kaiserpermanente.org/static/pdf/provider/clinical-review/infusion-site-care-policy.pdf

DRUG NAME	COVERAGE CRITERIA
FAM-TRASTUZUMAB DERXTECAN ADO-TRASTUZUMAB EMTANSINE	**Note: Must be administered in a non-hospital setting. See site of care policy* for criteria, reauthorization, and exceptions for new starts.**
PEMBROLIZUMAB* NIVOLUMAB*	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. ***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).**
PERTUZUMAB*	Note: Must be administered in a non-hospital setting. ~~**when used in combination with trastuzumab products. Site of Care does not apply if administered in combination with cytotoxic chemotherapy.**~~ 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).**
BORTEZOMIB* BEVACIZUMAB* BEVACIZUMAB-AWWB* BEVACIZUMAB-BVZR* BEVACIZUMAB-MALY*	Note: Must be administered in a non-hospital setting. ~~**when used as monotherapy.**~~ See site of care policy* for criteria, reauthorization, and exceptions for new starts. ~~Site of Care Exceptions: 2 doses within 2 months.~~ ***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).**
DENOSUMAB*	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).**

DRUG NAME	COVERAGE CRITERIA
TRASTUZUMAB* TRASTUZUMAB-ANNS* TRASTUZUMAB-DKST* TRASTUZUMAB-DTTB* TRASTUZUMAB-PKRB* TRASTUZUMAB-QYYP*	Note: Must be administered in a non-hospital setting. ~~**when used as monotherapy or in combination with pertuzumab.**~~ 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).**

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 12 years old or younger
2. Member is medically unstable based upon submitted clinical history. Examples include but are not limited to, cardiopulmonary conditions that may increase the risk of adverse reactions, inability to safely tolerate intravenous volume loads, unstable vascular access requiring ultrasound guidance
3. Previous experience of a severe adverse event following infusion. Examples include, but are not limited to, anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure
4. Continuing experience of adverse events that cannot be mitigated (e.g., not mitigated by pre-medications or by reducing the rate of infusion)
5. Physically and/or cognitively impaired such that a preferred site of care would impact the safety of the infusion
6. The member's home is not eligible for home infusion services, is deemed unsuitable for care by the home infusion provider, or the drug cannot be administered by home infusion service providers (if the drug cannot be administered in an infusion center, outside of the hospital).

Clinical documentation (e.g., infusion records, medical records) supporting an exception must be included (e.g., dates of prior anaphylactic experience, specific details of adverse reactions, and attempts to mitigate).

Exception Doses:

For all new coverage requests, Site of Care criteria shall be waived for the administration of the first dose for all drugs, to allow enough time to arrange for a non-hospital outpatient setting for the infusion. Further dose exceptions apply for new start patients or patients reinitiating therapy after 6 months or longer following discontinuation of therapy as identified in applicable codes.*

**This does not include when standard dosing between infusions is 6 months or longer*

Oncology Exceptions:

For patients transitioning from combination **with provider-administered chemotherapy** to monotherapy, Site of Care criteria shall be waived for the administration of the first dose. Note: combination therapy exceptions apply to drugs administered under the medical benefit only (e.g., drugs administered orally are not considered). Further dose exceptions are outlined within applicable codes in the Site of Care Policy.

Additional Information

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

Failure to obtain 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.

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