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May 21, 2025

FAM-TRASTUZUMAB (ENHERTU) AND ADO-TRASTUZUMAB EMTANSINE (KADCYLA) UPDATED PRIOR AUTHORIZATION CRITERIA

Dear Provider,

Fam-trastuzumab (Enhertu) and Ado-trastuzumab emtansine (Kadcyla) are on the **non-Medicare** list of office-administered drugs requiring prior authorization. **Effective September 1, 2025,** the quantity limit for fam-trastuzumab (Enhertu) and ado-trastuzumab emtansine (Kadcyla) will be updated. **This letter is a notification of the change in prior authorization criteria required before administering these medications in a physician's office.**

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.

Prior Authorization Criteria for fam-trastuzumab (Enhertu) (changes are in bold):

DRUG NAME	COVERAGE CRITERIA
Fam-trastuzumab	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 OR AR positive 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)

DRUG NAME	COVERAGE CRITERIA
	• If HR negative with PD-L1 positive (CPS ≥ 10): Previous therapy with pembrolizumab plus chemotherapy, until toxicity, 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. Colorectal Cancer: Covered for treatment of metastatic disease in patients who are Non-Oligometastatic (not candidates for curative intent therapy, i.e., liver ablation, lung/liver wedge resection, etc.) with HER2 amplification, if: • 3rd or 4th line therapy and: o Pan RAS mutated OR o Pan RAS wild type, No NRAF V600(x) mutation and failed Trastuzumab + Pertuzumab tucatinib 9. Biliary Tract Cancer: Treatment of unresectable/metastatic disease if: • Third line therapy AND • HER2 Positive IHC3+ 10. Esophageal Squamous Cell Metastatic Carcinoma: • Third line setting • Her2 positive IHC3+ 11. Covered for the treatment of Stage B/C hepatocellular carcinoma in the third line setting if: • HER2 Positive • Child Pugh A <u>Quantity Limit:</u> • Breast cancer: authorizations will be limited to a maximum dose of 5.4 mg/kg* every 21 days for 1 year. • **Gastric cancer: authorizations will be limited to a maximum dose of 6.4 mg/kg* every 21 days for 1 year.** • Requests for continuation of therapy will require documentation of disease stability (lack of progression). • ***The approved dose will be rounded down to the nearest vial size when the resulting reduction is less than 10% of the maximum allowed dose.** Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.

Prior Authorization Criteria for ado-trastuzumab emtansine (Kadcyla) (changes are in bold):

DRUG NAME	COVERAGE CRITERIA
Ado-trastuzumab emtansine	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:

DRUG NAME	COVERAGE CRITERIA
	• 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. <u>Quanty Limit:</u> • **Adjuvant breast cancer treatment (following neo-adjuvant use of trastuzumab-based treatment): authorizations will be limited to a maximum dose of 3.6 mg/kg* every 21 days for a maximum duration of 14 cycles.** • All **other** breast cancer indications: authorizations 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). • *** The approved dose will be rounded down to a dose consistent with the lowest vial size combination to minimize waste when the resulting reduction is less than 10% of the maximum allowed dose.** Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.

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