

## GCHP Medi-Cal Clinical Guidelines Ado-trastuzumab (Kadcyla™)

PA Criteria	Criteria Details
<b>Covered Uses (FDA approved indication)</b>	<ul style="list-style-type: none"> <li>For the treatment of patients with HER2 positive metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. They should have either: <ul style="list-style-type: none"> <li>Received prior therapy for metastatic disease, or</li> <li>Developed disease recurrence during or within six months of completing adjuvant therapy.</li> </ul> </li> <li>The adjuvant treatment of patients with HER2-positive early breast cancer who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment.</li> </ul>
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"> <li>Pregnancy</li> <li>Severe hepatic impairment (Child-Pugh class C)</li> <li>Pediatric patients</li> <li>Total bilirubin &gt;two times ULN at any time</li> <li>Nodular regenerative hyperplasia</li> <li>Symptomatic heart failure, grade 3 to 4 left ventricular systolic dysfunction, grade three to 4 heart failure, or grade 2 heart failure with LVEF &lt;45%</li> </ul>
<b>Required Medical Information</b>	<p><b>HER 2 Positive breast cancer – metastatic cancer</b> All of the following:</p> <ul style="list-style-type: none"> <li>Clinical notes or documentation confirming HER 2 positive diagnosis</li> <li>Documentation of previous therapy with trastuzumab and taxane</li> <li>Documentation of prior therapy for metastatic disease OR disease recurrence during or within six months of completing adjuvant therapy</li> </ul> <p><b>HER 2 Positive breast cancer – early cancer</b> All of the following:</p> <ul style="list-style-type: none"> <li>Clinical notes or documentation confirming HER 2 positive diagnosis AND</li> <li>Documentation of failure with previous therapy with trastuzumab and neoadjuvant taxane</li> </ul>
<b>Age Restriction</b>	18 years and older (For ages 18 – 21, check for CCS eligibility)
<b>Prescriber Restrictions</b>	Oncologist
<b>Coverage Duration</b>	Initial: Six months Renewal: 12 months
<b>Other Criteria / Information</b>	Criteria adapted from DHCS OCT 2024



	HCPCS	Description	Dosing, Units
	J9354	Injection, ado-trastuzumab emtansine, 1 mg	3.6mg/kg IV every three weeks.

STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	11/5/2024	11/5/2024	Pearl Okonkwo, Temp-Clinical Programs Pharmacist Yoonhee Kim, Interim Director of Pharmacy Services	N/A
Approved	N/A	11/14/2025	Pharmacy & Therapeutics (P&T) Committee	5/1/2025