

UPDATED CLINICAL CRITERIA FOR ACCESS TO TRASTUZUMAB

Access to be available in line with clinical criteria mentioned below, at authorised sites, prescribed by authorised prescriber (medical and/or radio- oncologist).

Indication

- Adjuvant treatment of HER-2 positive early stage breast cancer

Exclusions:

- Patients with locally advanced or metastatic breast cancer
- T1N0M0
- Patients with clinically significant comorbid diseases
- Cardiac ejection fraction < 55%
- Significant hepatic or renal dysfunction
- ECOG Performance Status > 1
- Patients who have only received adjuvant hormonal therapy with no adjuvant chemotherapy
- Pregnancy or lactation

Tests and screening

- Invasive breast cancer diagnosis (Biopsy specimen or histology of surgically resected specimen – segmentectomy or mastectomy)
- HER2 – positive 3+ **OR** HER2 – positive 2+/FISH positive
- Left ventricular ejection fraction (LVEF) evaluation \geq 55%

Regimen

	Medicine	Trastuzumab
	Route	Intravenous infusion
Dose	Initial	8mg/kg (<i>week 1</i>)
	Maintenance	6mg/kg (<i>from week 4</i>)
	Dosing cycle	3 weekly
	Duration	6 months

Monitoring and Treatment

- 3 weekly follow up for consult and treatment
- LVEF tests – baseline and at 6 months