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).

Programme facilitating access framework

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 ≥ 55%

Regimen

Medicine		Trastuzumab
Route		Intravenous infusion
Dose	**Initial**	8mg/kg *(week 1)*
	Maintenance	6mg/kg *(weeks 4-51)*
Dosing cycle		3 weekly
Duration		12 months

Monitoring and Treatment

- 3 weekly follow up for consult and treatment (17 - 18 sessions)
- LVEF tests (4) – every 4 months