

SUPREMO Eligibility Flowchart 2: After Neoadjuvant systemic therapy (NAST)

Main Exclusion Criteria:

1. 4 or more pathologically involved axillary nodes
 2. T3N1 or T4 tumours
 3. Bilateral Breast Cancer*
 4. Previous or concurrent malignancy (non-melanomatous skin cancer and in situ carcinoma of cervix are eligible)
 5. Male
 6. Pregnancy at time of radiotherapy
 7. Not fit for surgery, radiotherapy or adjuvant systemic therapy
 8. Unable or unwilling to give informed consent
- *see protocol for exceptions

Version 5 (prepared 29th Nov 10),
based on Protocol Version 29

*cTN stage denotes
radiological tumour stage*

*ypTN stage denotes
pathological stage after
NAST*

**Mastectomy
+
Axillary Node Procedure**
*NB nodes can come from the combination of procedures, before or after NAST.
Nodal status before NAST can be determined by axillary ultrasound, provided an axillary node procedure after NAST is performed*

Node Positive (N1)
(can include procedures before and after NAST, including nodes proven tumour positive on cytology pre-NAST). See also protocol on nodal scarring. (see protocol 7.3.3)

**Insufficient nodal staging
INELIGIBLE**

Node Negative (N0)

**0 involved nodes (before and after NAST)
Confirmed by Axillary Node Sample
(minimum 4 nodes examined in total)
Or Sentinel Node Biopsy**

**1-3 involved nodes
Confirmed by Axillary Node Clearance
With minimum 8 nodes examined in total**

**Insufficient nodes taken
INELIGIBLE**

**In total >3 involved nodes (from all procedures combined)
INELIGIBLE**

ELIGIBLE
Pathological tumour size ≤ 2cm (**ypT0 or ypT1**)
If pre NAST tumour size >2cm & ≤ 5cm (**cT2**)
Plus Grade 3 histology and/or Lymphovascular invasion
or
Also ELIGIBLE
Pathological tumour size >2cm & ≤ 5cm (**ypT2**)
Plus Grade 3 histology and/or Lymphovascular invasion (on pre or post NAST histology)
or
Also ELIGIBLE
If Radiological tumour size > 5cm (**cT3**) pre NAST, independent of grade & LVI (downstaging)

**Pre NAST clinical T4 tumour (any nodal stage):
INELIGIBLE**

Pathological tumour size ≤ 5cm (**ypT0, ypT1 or ypT2**)
ELIGIBLE
If pre NAST tumour size ≤ 5cm (**cT1 or cT2**)

Radiological (pre NAST) or Pathological (post NAST) tumour size > 5cm (**cT3 or ypT3**) or **cT4 or ypT4**
INELIGIBLE

Pathological tumour size > 5cm (**ypT3**)
If N0 both pre and post NAST histology
ELIGIBLE

Multifocal Tumours
For Multifocal tumours, follow the guide according to the diameter of the largest tumour focus (pre- or post-NAST)
Tumour stage pre NAST is determined by radiological investigations, not palpation (see protocol 7.2)