Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Trastuzumab emtansine

INITIATION – early breast cancer

Prerequisites (tick boxes where appropriate)

- ○ Patient has early breast cancer expressing HER2 IHC3+ or ISH+

and

- ○ Documentation of pathological invasive residual disease in the breast and/or auxiliary lymph nodes following completion of surgery

and

- ○ Patient has completed systemic neoadjuvant therapy with trastuzumab and chemotherapy prior to surgery

and

- ○ Disease has not progressed during neoadjuvant therapy

and

- ○ Patient has left ventricular ejection fraction of 45% or greater

and

- ○ Adjuvant treatment with trastuzumab emtansine to be commenced within 12 weeks of surgery

and

- ○ Trastuzumab emtansine to be discontinued at disease progression

and

- ○ Total adjuvant treatment duration must not exceed 42 weeks (14 cycles)

INITIATION – metastatic breast cancer

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- ○ Patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology)

and

- ○ Patient has previously received trastuzumab and chemotherapy, separately or in combination

and

- ○ The patient has received prior therapy for metastatic disease*

or

- ○ The patient developed disease recurrence during, or within six months of completing adjuvant therapy*

and

- ○ Patient has a good performance status (ECOG 0-1)

and

- ○ Patient does not have symptomatic brain metastases

or

- ○ Patient has brain metastases and has received prior local CNS therapy

and

- ○ Patient has not received prior funded trastuzumab emtansine treatment

and

- ○ Treatment to be discontinued at disease progression

CONTINUATION – metastatic breast cancer

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- ○ The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab emtansine

and

- ○ Treatment to be discontinued at disease progression

Note: *Note: Prior or adjuvant therapy includes anthracycline, other chemotherapy, biological drugs, or endocrine therapy.

I confirm that the above details are correct:

Signed: ..... Date: .....