HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

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 or trastuzumab deruxtecan treatment
  - **or**
    - ◯ Patient has discontinued trastuzumab deruxtecan due to intolerance
    - **and** ◯ The cancer did not progress while on trastuzumab deruxtecan
- **and** ◯ Treatment to be discontinued at disease progression

I confirm that the above details are correct:

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

HOSPITAL

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 *- continued*

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: ....