

3 May 2007

To All Pharmaceutical Suppliers, Hospital Pharmacists, Medical Groups  
and Interested Parties

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**Notification of widened access to trastuzumab (Herceptin) and docetaxel (Taxotere) on the Pharmaceutical Schedule for adjuvant treatment of HER 2 positive early breast cancer.**

PHARMAC is pleased to advise that the PHARMAC Board has approved the proposal to widen access to trastuzumab and docetaxel in Sections B and H of the Pharmaceutical Schedule. This means that:

**Trastuzumab:**

- From 1 July 2007 treatment with trastuzumab for HER 2 positive early breast cancer patients will be funded when it is administered for 9 weeks concurrently with taxane chemotherapy;
- The Special Authority for trastuzumab in Section B of the Pharmaceutical Schedule will be amended as follows from 1 July 2007 (changes in bold and strikethrough):

TRASTUZUMAB – PCT only – specialist  
Special Authority for Subsidy

Initial application (**metastatic breast cancer**) only from a relevant specialist. Approvals valid for 12 months where the patient has metastatic breast cancer expressing HER 2 ICH 3+ or FISH +.

Renewal (**metastatic breast cancer**) only from a relevant specialist. Approvals valid for 12 months ~~where the cancer has not progressed~~ **for applications meeting the following criteria:**

**Both:**

- 1 The patient has **metastatic breast cancer**; and
- 2 The cancer has not progressed.

**Initial application (early breast cancer) only from a relevant specialist. Approvals valid for 3 months for applicants meeting the following criteria:**

**All of the following:**

- 1 The patient has early breast cancer expressing HER 2 ICH 3+ or FISH +; and
- 2 Maximum cumulative dose of 20mg/kg (9 weeks treatment)\*; and
- 3 Trastuzumab is to be given concurrently with adjuvant taxane chemotherapy\*;  
and
- 4 Trastuzumab is not to be given concurrently with anthracycline chemotherapy.

**Notes:**

Indications marked with \* are unapproved indications.

It is recommended that for early breast cancer trastuzumab be administered concurrently with docetaxel prior to anthracyclines as per the FinHer regimen (Joensuu H, Kellokumpu-Lehtinen P, Bono P, et al. Adjuvant docetaxel or vinorelbine with or without trastuzumab for breast cancer. N Engl J Med 2006;354(8):809-20).

- Since administration with a taxane would be an unapproved indication for trastuzumab practitioners prescribing it in this manner should be aware of, and comply with, their obligations under Section 25 of the Medicines Act 1981.

**Docetaxel:**

- From 1 July 2007 docetaxel will be funded for early breast cancer patients when it is administered concurrently with trastuzumab;
- The Special Authority for docetaxel in Section B of the Pharmaceutical Schedule will be amended as follows from 1 July 2007 (changes in bold and strikethrough):

DOCETAXEL – PCT only – specialist  
Special Authority for Subsidy

Initial application only from a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Any of the following:

- 1 Both:
  - 1.1 The patient has ovarian, fallopian\* or primary peritoneal cancer\*; and
  - 1.2 Either:
    - 1.2.1 Has not received prior chemotherapy; or
    - 1.2.2 Has received prior chemotherapy but have not previously been treated with taxanes; or
- 2 The patient has metastatic breast cancer; or
- 3 **Both**
  - 3.1 **The patient has early breast cancer; and**
  - 3.2 **Docetaxel is to be given concurrently with trastuzumab; or**
- ~~34~~ Both
  - ~~3.14.1~~ The patient has non small-cell lung cancer; and
  - ~~3.24.2~~ Either:
    - ~~3.2.14.2.1~~ Has advancing disease (stage IIIa or above); or
    - ~~3.2.24.2.2~~ Is receiving combined chemotherapy and radiotherapy; or
- 45 Both:
  - 4.45.1 The patient has small-cell lung cancer\*; and
  - 4.25.2 Docetaxel is to be used as second-line therapy.

Renewal only from a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

- ~~56~~ The patient has metastatic breast cancer, non small-cell lung cancer, or small-cell lung cancer\* and;
  - ~~5.46.1~~ The patient requires continued therapy; or
  - ~~5.26.2~~ The tumour has relapsed and requires re-treatment.

Note indications marked with \* are unapproved indications.

We thank all those who submitted responses to consultation. If you have any questions about this change please call PHARMAC on 0800 66 00 50.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Jackie Evans', written in a cursive style.

Jackie Evans  
Therapeutic Group Manager