

20 March 2007

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

**CONSULTATION ON A PROPOSAL TO WIDEN ACCESS TO TRASTUZUMAB (HERCEPTIN) AND DOCETAXEL (TAXOTERE) FOR ADJUVANT TREATMENT OF HER 2 POSITIVE EARLY BREAST CANCER**

**The funding proposal**

PHARMAC is seeking feedback on a proposal to widen the access to trastuzumab and docetaxel to include adjuvant use for HER 2 positive early breast cancer.

If this proposal is approved by the PHARMAC Board it would result in PHARMAC subsidising treatment with trastuzumab for HER 2 positive early breast cancer patients when it is administered for 9 weeks concurrently with taxane chemotherapy.

**How do I make a submission?**

We are inviting feedback from anyone interested in this funding proposal. You can make submissions in writing to the addresses that follow. We welcome feedback by email, fax or post. The deadline for submissions is **5pm, Thursday 12 April 2007**.

By email: Send to [jackie.evans@pharmac.govt.nz](mailto:jackie.evans@pharmac.govt.nz)

By fax: Send to +64 (0) 4 460 4995

By mail: Send to Jackie Evans, PHARMAC, PO Box 10-254, Wellington.

**What will happen then?**

All of the submissions we receive will be taken into consideration before a recommendation is taken to PHARMAC's Board. The PHARMAC Board will then make a decision on this proposal for funding trastuzumab for HER 2 positive early breast cancer.

If a decision to fund is made, it is anticipated that the proposed changes would take effect from 1 June 2007 at the earliest.

**What are the details of the proposal?**

The following section outlines how the subsidy rules would be amended in the Pharmaceutical Schedule to permit funding as proposed.

The proposal is to amend the current Special Authority criteria for trastuzumab and docetaxel as follows (additions marked in bold and deletions as 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 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 3+ or FISH +; and
- 2 The patient has a normal Left Ventricular Ejection Fraction; and
- 3 Trastuzumab to be commenced within 12 weeks of surgery; and
- 4 Maximum cumulative dose of 20mg/kg (9 weeks treatment)\*; and
- 5 Trastuzumab is to be given concurrently with taxane chemotherapy\*; and
- 6 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).

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:
  - 4.15.1 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;
  - 5.16.1 The patient requires continued therapy; or
  - 5.26.2 The tumour has relapsed and requires re-treatment.

Note indications marked with \* are unapproved indications.

### **Where can I find more information?**

More detailed information on the proposal can be found on the PHARMAC website <http://www.pharmac.govt.nz>. You can also seek further information from the PHARMAC helpline, 0800 66 00 50.

We look forward to receiving your feedback on this proposal.

Yours sincerely



Jackie Evans  
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