

4 June 2010

Approval of proposal to amend the access criteria for trastuzumab (Herceptin) in the Pharmaceutical Schedule

PHARMAC has decided to list trastuzumab (Herceptin) in the Pharmaceutical Schedule for treatment courses of up to 12 months for patients with HER 2 positive early breast cancer.

In summary, from 1 July 2010:

- The Special Authority criteria for access to trastuzumab in the Pharmaceutical Schedule will be amended to allow access to DHB funding for treatment courses of up to 12 months for patients with HER 2 positive early breast cancer.

This decision will result in an administrative and funding shift from the Ministry of Health (the Ministry) to PHARMAC and District Health Boards providing one consistent funding mechanism for all subsidised trastuzumab treatment. The new administrative and funding arrangements will deliver administrative efficiencies to the health sector and improve data collection.

Detail of this decision

From 1 July 2010 the Special Authority restriction applying to all strengths of trastuzumab in Section B of the Pharmaceutical Schedule will be as follows:

Initial application — (metastatic breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months where the patient has metastatic breast cancer expressing HER-2 IHC 3+ or FISH+.

Renewal — (metastatic breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months 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 or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 15 months for applications meeting the following criteria:

All of the following:

- 1 The patient has early breast cancer expressing HER 2 IHC 3+ or ISH + (including FISH or other current technology); and
- 2 Maximum cumulative dose of 106mg/kg (12 months' treatment); and
- 3 Any of the following:
 - 3.1 9 weeks' concurrent treatment with adjuvant chemotherapy is planned;
or
 - 3.2 12 months' concurrent treatment with adjuvant chemotherapy is planned;
or

- 3.3 12 months' sequential treatment following adjuvant chemotherapy is planned; or
- 3.4 Other treatment regimen, in association with adjuvant chemotherapy, is planned.

Note: For patients with previous Special Authority approvals for a maximum cumulative dose of 20mg/kg (9 weeks treatment) granted after 1 April 2009 the approval period has been extended to allow claims for a maximum cumulative dose of 106mg/kg (12 months treatment)

The listed prices, subsidies and confidential rebates applying to trastuzumab will not change as a result of this decision.

Patients currently receiving Ministry of Health funded treatment for early breast cancer

All claims for trastuzumab dispensed to early breast cancer patients **prior to 1 July 2010** will continue to be processed under the current systems i.e. Special Authority for 9 weeks' treatment or invoice to the Ministry for 12 months' treatment.

All claims for trastuzumab dispensed to early breast cancer patients **from 1 July 2010** will require a valid Special Authority approval.

Patients with previous Special Authority approval

Patients currently receiving Ministry funded trastuzumab who do have (or have had) a previous early breast cancer Special Authority approval for trastuzumab (SA0885) granted after 1 April 2009, will automatically have their approval period extended to 15 months from the start date of the previous approval to allow claims for trastuzumab dispensed after 1 July 2010 to be paid. No action is necessary by the prescriber.

Patients without previous Special Authority approval

For patients currently receiving Ministry funded trastuzumab who do **not** have a previous early breast cancer Special Authority approval for trastuzumab (SA0885) a Special Authority application must be completed and an approval number issued, in order for claims for trastuzumab dispensed after 1 July 2010 to be paid. These applications can be completed either by:

- manually completing a Special Authority form and including the patient's actual treatment start date (i.e. the date prior to 1 July 2010) on the form, or
- completing a spreadsheet which may include details for multiple patients (please contact jackie.evans@pharmac.govt.nz for an electronic copy of this spreadsheet).
- Note: electronic Special Authority applications cannot be made for these patients.

Please note: Special Authority applications for these patients **must be completed by 31 July 2010**.

Monthly reporting to the Ministry of Health

DHBs should continue providing 12 months' and 9 weeks' Herceptin patient treatment volume data to the Ministry, as per current the process, for May and June 2010. The June report is due to the Ministry by 20 July 2010. Reporting is not required thereafter.

Feedback Received

We appreciate all the feedback we received during consultation and acknowledge the time people took to respond. All consultation responses received by the consultation closing date were considered in their entirety prior to making a decision on the proposal.

Consultation responses were generally supportive; however the following issues were raised in relation to specific aspects of the proposal:

Theme	PHARMAC Comment
<p>One responder considered that PHARMAC should review the requirement that funding be for patients with HER-2 IHC 3+ or FISH+ breast cancer because of the potential for false positives (estimated to be 12.9%). The respondent recommended that all IHC 3+ patients should have the results confirmed by FISH.</p>	<p>PHARMAC staff note that this proposal does not, and was not intended to, change the current funding and access conditions for patients. We do not consider it appropriate to review diagnostic requirements for funding at this time.</p>
<p>Some disagreed with the proposed criteria 3.4 '<i>any other treatment course is planned</i>'. It was noted that it should be clearer that trastuzumab should only be administered in association with adjuvant chemotherapy as per a recognised treatment regimen.</p>	<p>We agree that the evidence supports that trastuzumab should be given in association with adjuvant chemotherapy, rather than as monotherapy or in combination with hormone (or other) treatments and have amended the criteria accordingly.</p> <p>PHARMAC staff note that criteria 3.1-3.4 are intended to capture data on treatment plans. We note that treatment plans can change (for example a patient may initially want only 9 weeks' treatment and then wish to carry on and have 12 months' treatment). All patients with Special Authority approval will be eligible to receive funding for a maximum of 106 mg/kg (12 months' treatment) regardless of which criterion 3.1-3.4 is ticked on the Special Authority application form. No action is needed if a patient's treatment plan changes.</p>
<p>Some considered that the proposed approval period of 13 months was not sufficient for some patients. For example patients who receive 12 months' sequential adjuvant trastuzumab will have a 3 month period where they receive their anthracycline chemotherapy prior to commencing trastuzumab and it would be preferable to be able to complete Special Authority applications prior to a patient starting all chemotherapy.</p>	<p>We agree that it is administratively easier for Special Authority applications to be completed at the start of treatment. Although we consider that 13 months would be sufficient for most patients, we have amended the approval period to 15 months to allow for treatment delays.</p>

Theme	PHARMAC Comment
<p>One respondent requested “grand-parenting” for patients who have already commenced Ministry of Health funded 12 months’ treatment. The respondent noted that many patients will not have an existing Special Authority approval for trastuzumab; and considered that it was not reasonable to require clinicians to complete Special Authority forms for these patients.</p>	<p>From 1 July 2010 all claims for trastuzumab will require a valid Special Authority approval.</p> <p>It is not possible to ‘grandparent’ patients who have not previously received a Special Authority approval since the Ministry does not hold sufficient data regarding these patients, or the applying clinicians, in its systems. We note that clinicians can apply for a Special Authority for these patients either manually by completing a Special Authority form (including the patient’s actual treatment start date) or using a spreadsheet available from PHARMAC. Note electronic Special Authority applications for these patients cannot be made.</p> <p>We note that Special Authority applications for trastuzumab can be made either by a relevant specialist or any medical practitioner on the recommendation of a relevant specialist.</p>
<p>One respondent considered that if the Special Authority criteria include a 9 week option then it should retain an asterix indicating that 9 weeks is an ‘Unapproved Indication’</p>	<p>PHARMAC’s decision regarding the funding of 9 weeks concurrent trastuzumab has not changed. Therefore, it is appropriate for this option to remain in the Special Authority criteria.</p> <p>We note that in April 2007, when PHARMAC made its decision to fund 9 weeks concurrent trastuzumab, the Medsafe approved Datasheet in New Zealand did not cover concurrent treatment; the approved indication was for sequential treatment only. Subsequently the datasheet for trastuzumab has been amended to include concurrent treatment. Duration of treatment is not specified in the approved indication.</p>

More information

If you have any queries about these changes please contact the PHARMAC helpline on 0800 66 00 50 (9 am to 5 pm weekdays).