PHARMAC
Pharmaceutical Management Agency

Herceptin

Questions and Answers

7 August 2008

Is Herceptin funded in New Zealand?

Yes. New Zealanders continue to have fully funded access to an effective and full course of Herceptin treatment for HER2-positive early breast cancer – concurrent 9 week treatment with a taxane drug (docetaxel or paclitaxel).

About 350-400 New Zealand women are diagnosed with HER2-positive breast cancer each year, and these women are all eligible for this treatment.

Why is a concurrent 9 week course funded?

Herceptin for early breast cancer can be administered in two main ways: at the same time as (concurrently) or after (sequentially) other chemotherapy treatment.

There is a lot of debate internationally about the best way to administer Herceptin, but the current evidence shows that concurrent therapy probably provides a better result than sequential.

The 9 week course of Herceptin, concurrent with a taxane (chemotherapy), has been demonstrated to delay the recurrence of breast cancer with similar results to other ways of using Herceptin. A shorter course means less exposure to the treatment and perhaps reduced side effects, such as heart failure, than the longer duration treatments.

Is the funded 9 week treatment effective?

Yes. The FinHer trial demonstrated that 9 week Herceptin treatment delayed breast cancer returning in women with HER2-positive early breast cancer. FinHer, although smaller than other trials, is a scientifically robust study and its key results were statistically significant. The benefit of the 9 week treatment is comparable to the 12 month treatments for disease free survival.

Why not fund the 12 month treatments?

New Zealanders have access to a fully funded, effective Herceptin treatment for early HER2-positive breast cancer – the 9 week treatment. A fresh review of the science and other information has failed to convince us that the 12 month treatment offers any additional benefits over the 9 week treatment. To justify the additional expense, we first would need to be confident that 12 months treatment offered additional health outcomes, and we don't have that confidence.

The only way to tell for sure whether the additional cost (and risk) of extending treatment duration is worth it, is to conduct a head-to-head study. That is why we are financially supporting a study, the SOLD study.

PHARMAC sought advice on this issue from its expert clinical advisors, the Pharmacology and Therapeutics Advisory Committee ("PTAC"), PHARMAC's decision is consistent with that advice. Relevant PTAC Minutes are available on PHARMAC's website.

If the comparison of long vs short is so important, why has Roche not looked at it?

From PHARMAC's perspective, pharmaceutical suppliers should – as the companies that profit from selling medicines – do all they can to test different treatment regimens, including shorter treatments. It is not clear why 12 months became Roche's preferred treatment length, and not 11 months, 6 or even 9 weeks. The HERA study, funded by Roche, is looking at even longer duration of treatment (2 years).

Understanding the optimal treatment duration is often an issue for PHARMAC when funding medicines. PHARMAC must do all it can to consider all evidence before making decisions on what treatment approaches are best.

Why is NZ currently funding a different treatment regimen to other countries?

PHARMAC's role is to make funding decisions that are in the best interests of New Zealanders. This means making our own decisions independently of other countries.

In some countries, the 9 week treatment could not be considered for funding due to rules around their registration and funding processes, which means that they are not able to take into account all of the evidence.

Concurrent 9 week treatment with Herceptin is available as a treatment choice in some other countries, and international debate about the need for longer duration treatment continues – underscoring the uncertainty PHARMAC has found.

PHARMAC is helping to fund an international clinical trial (SOLD) to assess whether there are any additional treatment benefits from adding longer-duration treatment to a concurrent 9 week treatment regimen.

Didn't PHARMAC decide to not fund 12 months treatment long ago?

A group of eight women sought judicial review of PHARMAC's earlier decision-making in the High Court. In its decision, released in April 2008, the Court rejected all but one of the 28 points raised by the plaintiffs. The Court set aside PHARMAC's July 2006 decision to decline Roche's application for funding 12 months treatments with Herceptin for HER2-positive early breast cancer, and directed PHARMAC to make a new decision following consultation.

What was the process followed?

PHARMAC exceeded the requirements imposed on it by the High Court for this process. PHARMAC sought public feedback on a new proposal to decline funding for the 12 months treatments. In addition, PHARMAC:

- met face to face with a number of interested groups – including breast cancer patients and oncologists;

- considered a new bundled commercial offer from Roche, the supplier of Herceptin;

- sought advice from PTAC, and PTAC's cancer treatments sub-committee (CaTSoP) on new clinical information; and

- updated its budget impact and cost-utility analyses of Herceptin.

What did the new information or advice show?

More than 300 consultation responses were received. These came from individuals, groups representing patients, oncologists and oncology groups, public health medicine specialists and District Health Boards. Submissions were received from New Zealand and overseas. A summary of submissions, issues raised, and PHARMAC's responses, are available at www.pharmac.govt.nz.

PTAC and the cancer treatments sub-committee reviewed new clinical information from Herceptin studies N9831/B31 and a new study PACS04. PTAC members commented that the emerging data from studies seem to indicate that sequential 12 months treatment with trastuzumab (the treatment approved by Medsafe for New Zealand) may be a less effective use of the agent in treating HER2 positive early breast cancer patients. PTAC recommended that funding of 12 months treatments (sequential and concurrent) should be declined. PTAC's view was that no new information had been presented that demonstrated any additional health benefit over the currently funded concurrent 9 week treatment regimen. PTAC recommended that current funding for the 9 week treatment be continued.

The new commercial offer from Roche was also carefully considered.

Did PHARMAC consider all clinical evidence?

Yes, PHARMAC looked at all available evidence, both published and unpublished. PHARMAC is concerned about the selective publication of evidence around Herceptin (publication bias). These issues have been reported on in The Lancet medical journal, linked on PHARMAC's website. A full summary of the currently available clinical evidence is also available on the website.

What happens now?

The full and effective concurrent 9 week Herceptin treatment remains fully funded for all eligible New Zealanders as a complete treatment regimen. PHARMAC remains open to considering new information if and when it becomes available.