

Media release

Herceptin not funded, under continuing review

Funding has not yet been approved for breast cancer drug Herceptin, but will be kept under review by Government drug-funding agency PHARMAC as new information emerges.

The available clinical data is not sufficient to justify a positive funding decision, says spokeswoman Dr Dilky Rasiah. The data is unclear about Herceptin's long-term benefit and its impact on life expectancy.

District Health Boards, who fund pharmaceutical cancer drugs used in hospitals, accepted PHARMAC's recommendation to not fund Herceptin at this time.

The door remains open to funding Herceptin, but this would require better data, she says.

Dr Rasiah says PHARMAC is making every effort to obtain further information, including directly contacting clinical trial researchers in the United States and Finland. Two-year follow up data from the important HERA trial is also expected to be published in a peer reviewed journal by the end of this year.

In addition, discussions will be held with NZ oncologists on the possibility of New Zealand taking part in a further international trial on Herceptin.

Dr Rasiah says the first step in the ongoing review will occur in August when the clinical advisory committee PTAC will examine new information. PTAC's role is to provide clinical advice to PHARMAC. When it examined Herceptin at its May meeting, PTAC identified key uncertainties in the data and sought further information, some of which has been received.

"We are continuing to examine the evidence that is emerging," Dr Rasiah says. "At the moment the data is not strong enough to support a positive funding decision, although we are open to funding Herceptin if better quality evidence becomes available."

"The available data is short-term and does not show the long-term benefit of Herceptin, particularly on life expectancy. We need sufficient data that shows an investment in Herceptin is justified, which is not currently the case."

The high cost also remains a concern. Funding Herceptin for early breast cancer would cost DHBs \$20-\$25 million per year for up to 320 patients, compared to a current spend on all other hospital cancer drugs of about \$35-40 million.

District Health Boards support the decision made by PHARMAC, says DHB CEOs spokesman David Meates.

"DHBs have to be mindful of Herceptin's cost, and the impact funding would have on associated services such as echocardiograms, infusion and monitoring services," David Meates says.

"Herceptin is a high cost drug, and in considering a \$20-\$25 million investment such as this, we need to be sure that Herceptin offers sufficient benefit for its considerable cost. We don't have that confidence at the moment."

Dr Rasiah says PHARMAC is keeping a close eye on international developments.

In Britain, the National Institute of Clinical Excellence (NICE) has issued draft guidance recommending funding for Herceptin, however this guidance has been appealed. It will be a number of weeks before a final recommendation is made.

In Australia, the Pharmaceutical Benefits Advisory Committee has provisionally recommended funding for Herceptin, although this recommendation remains subject to price negotiations with Roche and final approval by the Australian Federal Cabinet. If approved, funding could occur from 1 December 2006.

Other countries also noted similar concerns to those raised by PHARMAC's clinical committee, says Dr Rasiyah.

For example, the independent report commissioned by NICE noted:

*"The benefits of trastuzumab (Herceptin) on rates of recurrence are unknown beyond three to four years; there is little evidence to date of the effects of trastuzumab on overall survival; and there is no evidence of the effects of trastuzumab upon long term cardiac dysfunction."*¹

Dr Rasiyah says in making a decision like Herceptin, PHARMAC and DHBs are aware that a \$20-25 million investment will limit their ability to fund other pharmaceuticals or health services. Other countries do not necessarily take into account the impact of spending on wider health services.

Dr Rasiyah says PHARMAC remains open to continuing negotiations with Roche and taking a further recommendation to District Health Boards. As Herceptin is a drug used in hospitals, funding must be approved by DHBs.

ENDS

Further information:

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¹ S. Ward et al. May 2006 "Trastuzumab for the Treatment of Primary Breast Cancer in Her2+ women". School of Health and Related Research, University of Sheffield.

Herceptin -- Questions and answers

Why is Herceptin not yet funded in NZ?

The evidence on Herceptin is not yet strong enough to enable PHARMAC to make a positive funding decision on Herceptin. PHARMAC remains open to funding the drug and will be continuously reviewing further evidence as it becomes available.

What did the expert clinical committee PTAC say about Herceptin?

In May, PTAC examined evidence on Herceptin and also the recommendation of its cancer treatments committee, Catsop. PTAC's view is that there is currently insufficient evidence to make a positive recommendation for funding, and has sought further information. PTAC is aware that more longer-term clinical data will soon be released.

PTAC will be re-examining Herceptin, including new information, at its August 2006 meeting.

What did the cancer treatments sub-committee (Catsop) say?

CaTSOP examined Herceptin in April. The Committee recommended Herceptin be listed on the Pharmaceutical Schedule with a low to medium priority. CaTSOP has examined a number of cancer medicines in the past and given them high priority for funding, for example imatinib (Glivec), rituximab (Mabthera), temozolomide (Temodal) and taxanes (breast cancer).

Why is there a difference between the Catsop and PTAC views?

Catsop is a sub-committee of PTAC with a narrower focus. PTAC encompasses broader clinical issues and is able to make comparisons with other treatments for other diseases.

PTAC and CaTSOP are independent, expert clinical advisory committees who make recommendations to PHARMAC. The committees do not make funding decisions (the PHARMAC Board does).

What issues were raised by PTAC?

PTAC found insufficient certainty in the evidence to make a positive recommendation for funding. PTAC was aware that more longer-term clinical data would soon be released, and considered this could enable a recommendation to be made.

PTAC was concerned that:

- The evidence did not provide certainty over how Herceptin would be used in clinical practice, including dosing schedule or duration of treatment. In particular, the FinHer Study suggested treatment duration could be reduced to around nine weeks, compared to the standard 12 months treatment.
- PTAC was unable to determine the size of treatment benefit on overall survival from the data produced.
- DHBs would have to fund additional resources to administer Herceptin, to carry out the required monitoring of cardiac function in Herceptin-treated patients (e.g. echocardiograms). This would be significant.
- Some of the data that the committee had requested from the supplier had not been provided.

Has further information been sought?

Yes. PHARMAC has sought detailed data from the continuing studies into Herceptin, including the HERA trial and the FinHer study (9 weeks' treatment). This has included approaches to Roche, to NZ clinicians involved in the trials, and directly to the researchers overseas.

What did PHARMAC recommend to DHBs?

In the absence of a positive recommendation from PTAC, PHARMAC recommended to DHBs that Herceptin not be funded at this time, and this recommendation was endorsed by DHBs.

How much does Herceptin cost?

Herceptin is a high cost drug, about \$70,000 per patient per year, or about \$20-\$25 million overall. In addition, because Herceptin carries an increased risk of heart failure there are associated costs such as echocardiograms (to monitor heart function), and hospital administration services.

By comparison, DHBs are budgeting about \$35-40 million for all cancer drugs this year.

DHBs are also aware that the extra services required as a result of widening access to Herceptin would come at the expense of other DHB services in other areas of health.

Has the cost-effectiveness of Herceptin been established?

Because only limited data is available on Herceptin, the drug's long-term value in economic terms is difficult to establish. PHARMAC has conducted an economic analysis, using a range of assumptions, to give an indication of its value.

The price of the treatment is significant, so if the price was to reduce then the cost-effectiveness figure would improve accordingly.

What is the situation in other countries?

Herceptin is not yet funded for early breast cancer in Britain or Australia.

The UK medicines assessment agency, NICE, has released its draft recommendation on Herceptin for early breast cancer. The draft paper recommends Herceptin be funded for early breast cancer. The draft recommendation is now subject to an appeal.

The assessment of Herceptin by NICE was very similar to PHARMAC's assessment, in that they both identified similar degrees of risk surrounding benefits and costs.

NICE has made its recommendation because it does not take into account wider health sector costs, as PHARMAC does. NICE also does not manage a capped budget.

In Australia, the Pharmaceutical Benefits Advisory Committee has released a draft recommendation to fund Herceptin for early breast cancer. Funding must be approved by the Australian Federal Cabinet. If approved, Herceptin could be funded in Australia from 1 December 2006.

Why is New Zealand in a different position to other countries?

Funding in New Zealand takes place within a budget (in this case the budget of DHBs), so choices have to be made about how to allocate spending. PHARMAC and DHBs are aware that committing \$20-25 million on Herceptin will limit the ability to fund other health services or pharmaceuticals, so a careful choice has to be made.

Most other countries, including the UK and Australia, do not have a capped budget. NICE makes its recommendations independent of funding considerations. However, in examining the case for funding Herceptin, an independent UK report commissioned by NICE noted four key concerns including the limited scope of the data and uncertainty around the benefits.

What happens next?

PHARMAC will maintain an ongoing review to ensure new information is assessed as soon as it becomes available. The first step will be PHARMAC seeking further advice from PTAC. Should a

positive recommendation be made, discussions can continue with the supplier, Roche, and a further recommendation on whether or not Herceptin should be funded can be made from PHARMAC to District Health Boards. Because Herceptin is a drug used in hospitals, funding has to be approved by District Health Boards.