Herceptin (trastuzumab): The NZ debate

Country: New Zealand
Partner Institute: The University of Auckland
Survey no: (11)2008
Author(s): Toni Ashton (CHSRP) and Sue Wells
Health Policy Issues: Pharmaceutical Policy, Benefit Basket

Current Process Stages

<table>
<thead>
<tr>
<th>Idea</th>
<th>Pilot</th>
<th>Policy Paper</th>
<th>Legislation</th>
<th>Implementation</th>
<th>Evaluation</th>
<th>Change</th>
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</thead>
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1. Abstract

There is controversy in New Zealand about the appropriate treatment regimen for Herceptin (trastuzumab) when used in the treatment of early HER2-positive breast cancer. There are questions about optimal duration and sequencing of treatment, and the long term benefits and risks. The drug is costly and the absolute benefit appears small. While most countries are funding a 12 month regimen, NZ has agreed to fund only nine weeks of treatment when given concurrently with a taxane chemotherapy.

2. Purpose of health policy or idea

Herceptin (trastuzumab) has been funded in New Zealand for the treatment of advanced stage HER2-positive breast cancer since 2002. Six randomised controlled clinical trials have compared adjuvant Herceptin with standard chemotherapy in the treatment of early HER2-positive breast cancer. Most have shown statistically significant benefits in terms of disease-free survival and life expectancy. However, the results of one trial have suggested that 12 months of treatment may not provide any additional benefits over 9 weeks of treatment. The trials indicate that Herceptin treatment administered concurrently with other chemotherapy may be more effective than sequential treatment.

The drug is expensive - around USD70,000 per annum for 12 months treatment - and treatment increases the risk of heart failure. The absolute benefits of treatment also appear to be quite small with increases in disease-free survival occurring in only about 4-6 out of 100 women. Questions therefore remain about the optimal duration of treatment, dosage and sequencing of treatment, how to minimise cardiac toxicity, and long term clinical outcomes.

There are variations in the way that Herceptin is used around the world. While it is approved for use concurrently with a taxane in the USA, in Europe it is licensed for use after all chemotherapy is completed. More than 30 countries have agreed to fund a 12 month regimen as this is the recommended dose of the manufacturers. However in July 2007, Pharmac (the agency that manages the funding of drugs in New Zealand) opted to take a different path from other countries and approved funding for a 9-week course of treatment only, given concurrently with taxane chemotherapy.

Groups affected
Patients with early stage HER2-positive breasts cancer, Pharmac, District Health Boards (who are responsible for
3. Characteristics of this policy

<table>
<thead>
<tr>
<th>Degree of Innovation</th>
<th>traditional</th>
<th>innovative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degree of Controversy</td>
<td>consensual</td>
<td>highly controversial</td>
</tr>
<tr>
<td>Structural or Systemic Impact</td>
<td>marginal</td>
<td>fundamental</td>
</tr>
<tr>
<td>Public Visibility</td>
<td>very low</td>
<td>very high</td>
</tr>
<tr>
<td>Transferability</td>
<td>strongly system-dependent</td>
<td>system-neutral</td>
</tr>
</tbody>
</table>

4. Political and economic background

There has been much public pressure on public funding agencies to fund Herceptin for early stage breast cancer treatment, especially in New Zealand, the UK, Canada and Australia. In New Zealand, Pharmac bases its funding decisions on a number of criteria, including cost-effectiveness and overall cost to the health system. Funding 12 months of treatment would increase government expenditure on cancer treatment by 65%, from NZD47 million to around NZD77 million per year. Pharmac therefore considered that a 12 month treatment regimen was not a funding option, given:

- the fact that trials indicate that similar benefits may be achieved after 9 weeks of treatment;
- the uncertainty surrounding its long term benefits;
- the increased risk of cardiac toxicity associated with longer treatment;
- the high cost per quality adjusted life year (QALY), and
- the high budgetary impact. In New Zealand, District Health Boards must pay for cancer treatments out of a fixed annual budget. Any funding decisions therefore also have implications for the wider health system.

One group of eight breast cancer patients - some of whom have paid for their own 12-month treatments and who call themselves Herceptin Heroines - called for a judicial review into Pharmac's decision. In April 2008, the High Court found that Pharmac had not undertaken proper consultation in making its decision. Pharmac must therefore review its decision not to fund 12 months of treatment.

5. Purpose and process analysis

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<th>Change</th>
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</thead>
</table>
**Initiators of idea/main actors**

- Providers
- Payers
- Patients, Consumers: The opinions of consumer groups are divided
- Civil Society

**Stakeholder positions**

The decision by Pharmac to fund only 9 weeks of treatment when given in combination with a taxane has been highly controversial. Stakeholder positions can be broadly summarised as follows:

**Pharmac:** Although Pharmac has made the decision to limit funding to a 9-week regimen, they remain open to funding longer durations of treatment if it can be shown that this is cost-effective. They have pledged funding support for a clinical trial which compares the long and short durations of concurrent treatment.

**District Health Boards:** Are strongly supportive. The decision provides them with the ability to offer cancer patients a treatment that is both effective and affordable.

**Breast Cancer Consumer Groups:** Some groups are strongly opposed with protests including a march on parliament.

**Other women's health groups** are more neutral in their views and have drawn attention to the uncertainties associated with the results of the trials, the potential risks and the importance of basing funding decisions on good evidence.

**Pharmaceutical industry:** Roche, the manufacturer of Herceptin, is strongly opposed both to Pharmac's decision and to any further clinical trials.

**Oncologists:** Have mixed views. While they have concerns about the short duration of treatment, they are also concerned about the increased risk of cardiac toxicity associated with 12 months of treatment. Many would support further clinical trials.

**The media:** Have generally been opposed to Pharmac's decision, with coverage focussing on individual stories of women with breast cancer who want the longer course of treatment.

**Actors and positions**

Description of actors and their positions

- **Providers**
  - Pharmaceutical industry: very supportive
  - Cancer specialists: very supportive

- **Payers**
  - District Health Boards: very supportive

- **Patients, Consumers**
  - Breast cancer consumer groups: very supportive
  - Some other women's groups: very supportive

- **Civil Society**
## Actors and influence

Description of actors and their influence

### Providers
- **Pharmaceutical industry**: very strong
- **Cancer specialists**: very strong

### Payers
- **District Health Boards**: very strong

### Patients, Consumers
- **Breast cancer consumer groups**: very strong
- **Some other women's groups**: very strong

### Civil Society
- **Pharmac**: very strong

### Positions and Influences at a glance

<table>
<thead>
<tr>
<th>Positions</th>
<th>Influence</th>
</tr>
</thead>
<tbody>
<tr>
<td>very supportive</td>
<td>none</td>
</tr>
<tr>
<td>strongly opposed</td>
<td>very strong</td>
</tr>
</tbody>
</table>

- **1. District Health Boards**
- **2. Pharmac**
- **3. Some other women's groups**
- **4. Cancer specialists**
- **5. Breast cancer consumer groups**
- **6. Pharmaceutical industry**
6. Expected outcome

Following the judicial review Pharmac is now required to review its original funding decision. While this will require wider consultation, it seems unlikely that Pharmac will change from its original decision to fund 9 weeks of treatment unless new evidence becomes available. Five year follow-up results from one of the trials that involved 9 weeks of concurrent therapy should be available soon. It may not be possible to undertake further trials of a 9-week course as these are not supported by the manufacturer, Roche. It would also require oncologists in New Zealand and elsewhere to be willing and able to enrol patients in a clinical trial.

<table>
<thead>
<tr>
<th>Quality of Health Care Services</th>
<th>marginal</th>
<th>fundamental</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level of Equity</td>
<td>system less equitable</td>
<td>system more equitable</td>
</tr>
<tr>
<td>Cost Efficiency</td>
<td>very low</td>
<td>very high</td>
</tr>
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</table>

Only around 400 women are expected to be eligible for early stage treatment with Herceptin each year. The overall impact on the health system is therefore expected to be very low.

7. References

Sources of Information


Author/s and/or contributors to this survey

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Suggested citation for this online article