Factsheet for Healthcare Professionals

Biosimilar Trastuzumab on the Pharmaceutical Benefits Scheme

Ogivri® is a new brand of trastuzumab listed on the Pharmaceutical Benefits Scheme (PBS) on 1 August 2019. It is a biosimilar to the reference biological medicine Herceptin®.

Ogivri® has been assessed by the Therapeutic Goods Administration on the basis of comparability and clinical studies to be highly similar to Herceptin®. This means Ogivri® and Herceptin® provide the same health outcomes and are as safe and effective as each other.

What is trastuzumab?

Trastuzumab is a biological medicine used to treat breast and gastric cancer. Trastuzumab is supplied on the PBS under the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* and can only be prescribed by specialists.

The two trastuzumab brands are dosed the same. Herceptin® is available in 60mg and 150mg vials for infusion and Ogivri® is available in 150mg vials for infusion.

Details of the PBS prescribing restrictions are available in the *online Schedule of Pharmaceutical Benefits*, or in your prescribing software.

What is a biological medicine?

Biological medicines, including biosimilars, contain active substances derived from living cells or organisms. Compared to synthetic chemical medicines, biological medicines are more complex and have an inherent degree of minor variability in the production process. This means no two batches of a biological medicine (even from the same manufacturer) are ever exactly the same.

What is a biosimilar medicine?

Biosimilar medicines are highly similar versions of an already registered reference brand of a biological medicine.

Biosimilar medicines are designed and engineered to be as similar as possible to the reference biological medicine. There may be minor differences (known as molecular microheterogeneity) due to natural variability and the more complex manufacturing processes required for biological medicines. Importantly, these minor differences do not affect the safety, quality or effectiveness of the biosimilar medicine.

For a biosimilar medicine to be approved, the structural variability of the biosimilar medicine and the reference biological medicine, and all critical quality attributes (i.e. those important for the function of the molecule) must be highly similar.

Trastuzumab and PBS brand substitution

The independent expert Pharmaceutical Benefits Advisory Committee (PBAC) recommended Ogivri® be listed on the PBS as a substitutable biosimilar of the Herceptin® reference brand of trastuzumab. *Note: Ogivri® is **not** substitutable with Herceptin SC®.*

When PBS brands are listed as substitutable with each other, the pharmacist may dispense any brand, provided the prescriber has not indicated 'brand substitution not permitted', and they have permission from the patient.

Who chooses whether the biosimilar brand is used?

In Australia, trastuzumab infusions are administered in a hospital or clinic. The choice of brand generally used in a hospital clinic may be based on medicine purchasing decisions made by a clinician-led committee. Specific patient requirements will remain for discussion between a patient and treating clinician.

Prescribers are encouraged to discuss biosimilar medicines with patients. See *"How do I talk to patients about biosimilar medicines?"* in the 'Information for health care professionals' FAQs on the Department of Health website.

Why are biosimilar medicines important?

The PBS is a key element of Australia's National Medicines Policy which aims to deliver timely access to medicines at a cost that individuals and the community can afford.

Increasing costs associated with very expensive new health technologies, and the increasing prevalence of chronic conditions, is putting pressure on the sustainability of the PBS. Seven of the ten most expensive medicines subsidised by the PBS in 2017-18 were biological medicines with a combined cost of $1.53 billion. The cost to Government for trastuzumab alone in 2017-18 was $169.40 million.

Increasing use of biosimilar medicines is expected to deliver significant savings, due to price competition in the market. These savings can be reinvested into other areas of the Australian health system, expand access to biologic medicines as they become more affordable, and reduce the risk of medicine shortages.

Where can I find more Information?

The biosimilars page on the *Australian Government Department of Health website*

The biosimilars regulation page on the *Therapeutic Goods Administration website*

The PBAC Public Summary Document for Ogivri® on the *PBS website*

The Biosimilar Education Hub