Pharmaceutical Benefits Scheme – Biosimilar Trastuzumab

The following biosimilars brands of trastuzumab are listed on the Pharmaceutical Benefits Scheme (PBS):

Brand name	Date listed on PBS
Ogivri®	1 August 2019
Herzuma®	1 November 2019
Kanjinti®	1 December 2019
Ontruzant®	1 January 2020
Trazimera®	1 May 2020

These brands are listed under the Efficient Funding of Chemotherapy (EFC) arrangements of the Section 100 Highly Specialised Drugs Program (HSD Program).

What are biological and biosimilar medicines?

Biological medicines, including biosimilars, contain substances made by living cells or organisms. They are more complex to make than synthetic chemical medicines.

A biosimilar medicine is a highly similar version of a reference biological medicine, which is invariably the first brand to market. Biosimilar medicines are used to treat the same diseases, in the same way, as the reference biological medicines.

Biosimilar medicines have been tested and shown to be as safe and effective as the reference biological medicines.

How is biosimilarity determined?

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 by the Therapeutic Goods Administration (TGA), 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. There must also be no clinically meaningful differences identified in clinical studies comparing the biosimilar and reference products.

The biosimilar brands have been assessed by the TGA on the basis of comparability and clinical studies to be highly similar to the reference brand, Herceptin®. This means that Ogivri, Herzuma, Kanjinti, Ontruzant and Trazimera provide the same health outcomes and are as safe and effective as Herceptin.

Herceptin was removed from the PBS at the request of the pharmaceutical company which supplies this brand on 1 October 2021.

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* as an infusion and is prescribed by specialists. It is also available in the presentation Herceptin SC® as a solution for subcutaneous injection on the PBS General Schedule and HSD (Related Benefits) Program.

All trastuzumab brands for infusion are dosed the same and are available on the PBS in the following strengths:

Brand	Form and strength
Kanjinti®	150mg and 420mg vials for infusion
Herzuma®	150mg vials for infusion
Ogivri®	150mg vials for infusion
Ontruzant®	150mg vials for infusion
Trazimera®	60mg and 150mg vials for infusion

More information about this medicine is available by entering ‘trastuzumab’ at the NPS MedicineWise Medicine Finder.

Can PBS brands of trastuzumab be substituted?

The PBAC recommended that biosimilar brands be listed on the PBS as substitutable biosimilars of Herceptin, the reference brand of trastuzumab. As Herceptin is no longer available, the remaining brands available on the PBS are substitutable with each other where forms and strengths are equivalent. *Note: These brands are 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’ on the prescription, and they have permission from the patient.

What are the PBS restrictions for trastuzumab?

From 1 October 2019, following advice from the independent, expert Pharmaceutical Benefits Advisory Committee (PBAC), all brands of trastuzumab are now listed on the PBS to allow prescribing as an Authority Required (STREAMLINED) item.

Further listing changes from 1 October 2019 allow adjuvant or neo-adjuvant treatment for early breast cancer, and treatment in combination with any platinum chemotherapy for advanced gastric cancer.

Read the Schedule of Pharmaceutical Benefits for the restrictions for trastuzumab. The Schedule is also available via the PBS publications page. The prescribing software contains further details of initial and continuing treatment phase criteria and eligibility details. Over time PBS listing details may change – please consult the Schedule for current information.

Why are biosimilar medicines important?

The growing cost of new and innovative medicines, including biological medicines, continues to put pressure on the financial sustainability of the PBS. Eight of the ten most expensive medicines subsidised by the PBS in 2020-21 were biological medicines with a combined cost of $2.41 billion. The introduction of biosimilars on the PBS can help relieve this pressure.

How can greater use of biosimilars benefit the PBS?

The introduction of brand competition into the market leads to lower PBS prices, due to Price Disclosure and other statutory price reductions to PBS medicines. Under Price Disclosure arrangements the PBS subsidy is adjusted twice a year to reflect average market prices. As these become lower through competition, the prices of medicines that have at least one other brand on the PBS can be reduced. A price reduction only occurs if the weighted average discounting across all brands of a drug is greater than set percentages.

Savings from statutory price reductions to PBS medicines are being re-invested in the PBS, ensuring all Australians continue to have the earliest possible access to new medicines. All Australian patients benefit from rapid, equitable and sustainable access to the most effective medicines through the PBS.

Detailed information about PBS pricing, including Price Disclosure, is available on the PBS website.

More Information

For more information, read:

- Department of Health and Aged Care website About medicines page.
- Therapeutic Goods Administration website biosimilars medicines regulation.
- PBS website – PBAC Public summary document for Herzuma.
- PBS website – PBAC Public summary document for Kanjinti.
- PBS website – PBAC Public summary document for Ogivri.
- PBS website – PBAC Public summary document for Ontruzant.
- PBS website – PBAC Public summary document for Trazimera.
- The Biosimilar Education Hub (Generic and Biosimilar Medicines Association Education website, originally funded by the Australian Government).

Further information for healthcare professionals regarding the use of PBS Authorities and claiming of PBS benefits is available at the Services Australia website.