



**Australian Government**

**Department of Health**

**Information for Healthcare Professionals  
Pharmaceutical Benefits Scheme - New Biosimilar TRASTUZUMAB**

Trazimera<sup>®</sup> is a brand of trastuzumab that was listed on the Pharmaceutical Benefits Scheme (PBS) on 1 May 2020.

Trazimera<sup>®</sup> joins the following brands currently listed on the PBS:

| <b>Brand name</b>      | <b>Date listed on PBS</b> | <b>Brand status</b> |
|------------------------|---------------------------|---------------------|
| Herceptin <sup>®</sup> | 1 October 2006            | Reference           |
| Ogivri <sup>®</sup>    | 1 August 2019             | Biosimilar          |
| Herzuma <sup>®</sup>   | 1 November 2019           | Biosimilar          |
| Kanjinti <sup>®</sup>  | 1 December 2019           | Biosimilar          |
| Ontruzant <sup>®</sup> | 1 January 2020            | Biosimilar          |

The biosimilar brands of trastuzumab have been assessed by the Therapeutic Goods Administration (using comparability and clinical studies) to be highly similar to the reference brand, Herceptin<sup>®</sup>. This means that the biosimilars and Herceptin<sup>®</sup> provide the same health outcomes and are as safe and effective as each other.

**Amended PBS listings 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.

A summary of the trastuzumab PBS listing amendments for each indication is provided in the **table below**.

Refer to the Schedule of Pharmaceutical Benefits, available [online](#), in [PDF](#) and in prescribing software, for detailed information on the PBS prescribing restrictions.

**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<sup>®</sup> as a solution for subcutaneous injection on the PBS General Schedule (s85) and s100 (Related Benefits) Program.

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

| <b>Brand</b>           | <b>Form and strength</b>          |
|------------------------|-----------------------------------|
| Herceptin <sup>®</sup> | 60mg and 150mg vials for infusion |

|            |                                    |
|------------|------------------------------------|
| 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  |

### **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.

### **Prescriber choice and brand substitution**

The PBAC recommended that biosimilar brands be listed on the PBS as substitutable biosimilars of the Herceptin® reference brand of trastuzumab. *Note: These brands are not substitutable with Herceptin SC®.*

Prescribers retain, in consultation with their patient, the choice of which brand to prescribe. 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, infusions of trastuzumab are administered in a hospital or clinic. The choice of brand generally used in a hospital or 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 Australian Government 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. Eight of

the ten most expensive medicines subsidised by the PBS in 2018-19 were biological medicines with a combined cost of \$1.87 billion. The cost to Government for trastuzumab alone in 2018-19 was \$163.8 million.

Increasing the use of biosimilar medicines is expected to deliver significant reductions in the cost of the PBS, due to price competition in the market. This can improve the Government's capacity to fund expanded access to biological 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 PBAC Public Summary Document for Herzuma® on the [PBS website](#)

The PBAC Public Summary Document for Kanjinti® on the [PBS website](#)

The PBAC Public Summary Document for Ontruzant® on the [PBS website](#)

The PBAC Public Summary Document for Trazimera® on the [PBS website](#)

[The Biosimilar Education Hub](#)

## TABLES

For Authority Required (Streamlined) listings, prescribers need to request authority approval from Services Australia (formerly the Department of Human Services) to prescribe increased quantity and/or repeats in line with the PBS restriction.

### Trastuzumab EFC (Public) PBS Listings Summary

*PBS listing changes from 1 May 2020, incorporating the listing of Trazimera®. The following items are **Authority Required (STREAMLINED)**.*

| Form / Strength  | Brand  | Indication                        | Treatment Phase                         | Authority Level/Code | PBS Item Code for Claiming |
|--|--|-----------------------------------|---|----------------------|----------------------------|
| 60mg and 150mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg and 420mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg injection, 1 vial<br>60mg and 150mg injection, 1 vial | Herceptin<br>Herzuma<br>Kanjinti<br>Ogivri<br>Ontruzant<br>Trazimera | Early HER2 positive breast cancer | Initial treatment (weekly regimen)      | Streamlined (10296)  | 4632T                      |
| 60mg and 150mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg and 420mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg injection, 1 vial<br>60mg and 150mg injection, 1 vial | Herceptin<br>Herzuma<br>Kanjinti<br>Ogivri<br>Ontruzant<br>Trazimera | Early HER2 positive breast cancer | Continuing treatment (weekly regimen)   | Streamlined (10213)  | 4639E                      |
| 60mg and 150mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg and 420mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg injection, 1 vial<br>60mg and 150mg injection, 1 vial | Herceptin<br>Herzuma<br>Kanjinti<br>Ogivri<br>Ontruzant<br>Trazimera | Early HER2 positive breast cancer | Continuing treatment (3 weekly regimen) | Streamlined (10294)  | 4703M                      |

| Form / Strength  | Brand  | Indication  | Treatment Phase                      | Authority Level/Code | PBS Item Code for Claiming |
|--|--|---|--------------------------------------|----------------------|----------------------------|
| 60mg and 150mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg and 420mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg injection, 1 vial<br>60mg and 150mg injection, 1 vial | Herceptin<br>Herzuma<br>Kanjinti<br>Ogivri<br>Ontruzant<br>Trazimera | Metastatic (Stage IV)<br>HER2 positive breast cancer  | Initial treatment                    | Streamlined (9353)   | 10391X                     |
| 60mg and 150mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg and 420mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg injection, 1 vial<br>60mg and 150mg injection, 1 vial | Herceptin<br>Herzuma<br>Kanjinti<br>Ogivri<br>Ontruzant<br>Trazimera | Metastatic (Stage IV)<br>HER2 positive breast cancer  | Continuing treatment                 | Streamlined (9349)   | 10401K                     |
| 60mg and 150mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg and 420mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg injection, 1 vial<br>60mg and 150mg injection, 1 vial | Herceptin<br>Herzuma<br>Kanjinti<br>Ogivri<br>Ontruzant<br>Trazimera | Metastatic (Stage IV)<br>HER2 positive adenocarcinoma of the stomach or gastro-oesophageal junction | Initial treatment                    | Streamlined (9573)   | 10581X                     |
| 60mg and 150mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg and 420mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg injection, 1 vial<br>60mg and 150mg injection, 1 vial | Herceptin<br>Herzuma<br>Kanjinti<br>Ogivri<br>Ontruzant<br>Trazimera | Metastatic (Stage IV)<br>HER2 positive adenocarcinoma of the stomach or gastro-oesophageal junction | Continuing treatment                 | Streamlined (9571)   | 10588G                     |
| 60mg and 150mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg and 420mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg injection, 1 vial<br>60mg and 150mg injection, 1 vial | Herceptin<br>Herzuma<br>Kanjinti<br>Ogivri<br>Ontruzant<br>Trazimera | Early HER2 positive breast cancer   | Initial treatment (3 weekly regimen) | Streamlined (10293)  | 4650R                      |

## Trastuzumab EFC (Private) PBS Listings Summary

PBS listing changes from 1 May 2020, incorporating the listing of Trazimera®. The following items are **Authority Required (STREAMLINED)**.

| Form / Strength   | Brand   | Indication  | Treatment Phase                         | Authority Level/Code | PBS Item Code for Claiming |
|---|---|---|---|----------------------|----------------------------|
| 60mg and 150mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg and 420mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg injection, 1 vial<br>60mg and 150mg injection, 1 vial                  | Herceptin<br>Herzuma<br>Kanjinti<br>Ogivri<br>Ontruzant<br>Trazimera              | Early HER2 positive breast cancer                 | Initial treatment (weekly regimen)      | Streamlined (10296)  | 7264H                      |
| 60mg and 150mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg and 420mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg injection, 1 vial<br>60mg and 150mg injection, 1 vial                  | Herceptin<br>Herzuma<br>Kanjinti<br>Ogivri<br>Ontruzant<br>Trazimera              | Early HER2 positive breast cancer                 | Continuing treatment (weekly regimen)   | Streamlined (10213)  | 7265J                      |
| 150mg injection, 1 vial<br>60mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg and 420mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg injection, 1 vial<br>60mg and 150mg injection, 1 vial | Herceptin<br>Herceptin<br>Herzuma<br>Kanjinti<br>Ogivri<br>Ontruzant<br>Trazimera | Early HER2 positive breast cancer                 | Continuing treatment (3 weekly regimen) | Streamlined (10294)  | 7267L                      |
| 60mg and 150mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg and 420mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg injection, 1 vial<br>60mg and 150mg injection, 1 vial                  | Herceptin<br>Herzuma<br>Kanjinti<br>Ogivri<br>Ontruzant<br>Trazimera              | Metastatic (Stage IV) HER2 positive breast cancer | Continuing treatment                    | Streamlined (9349)   | 10383L                     |

| Form / Strength  | Brand  | Indication  | Treatment Phase                      | Authority Level/Code | PBS Item Code for Claiming |
|--|--|---|--------------------------------------|----------------------|----------------------------|
| 60mg and 150mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg and 420mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg injection, 1 vial<br>60mg and 150mg injection, 1 vial | Herceptin<br>Herzuma<br>Kanjinti<br>Ogivri<br>Ontruzant<br>Trazimera | Metastatic (Stage IV)<br>HER2 positive breast cancer  | Initial treatment                    | Streamlined (9353)   | 10402L                     |
| 60mg and 150mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg and 420mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg injection, 1 vial<br>60mg and 150mg injection, 1 vial | Herceptin<br>Herzuma<br>Kanjinti<br>Ogivri<br>Ontruzant<br>Trazimera | Metastatic (Stage IV)<br>HER2 positive adenocarcinoma of the stomach or gastro-oesophageal junction | Initial treatment                    | Streamlined (9573)   | 10589H                     |
| 60mg and 150mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg and 420mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg injection, 1 vial<br>60mg and 150mg injection, 1 vial | Herceptin<br>Herzuma<br>Kanjinti<br>Ogivri<br>Ontruzant<br>Trazimera | Metastatic (Stage IV)<br>HER2 positive adenocarcinoma of the stomach or gastro-oesophageal junction | Continuing treatment                 | Streamlined (9571)   | 10597R                     |
| 60mg and 150mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg and 420mg injection, 1 vial<br>150mg injection, 1 vial<br>150mg injection, 1 vial<br>60mg and 150mg injection, 1 vial | Herceptin<br>Herzuma<br>Kanjinti<br>Ogivri<br>Ontruzant<br>Trazimera | Early HER2 positive breast cancer   | Initial treatment (3 weekly regimen) | Streamlined (10293)  | 7266K                      |

Note that under section 33(2) of the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011*, chemotherapy medicines supplied under the Efficient Funding of Chemotherapy program may be substituted with a different brand of the same chemotherapy medicine. These medicines are not marked with 'a'-flags in the Schedule of Pharmaceutical Benefits.

For more detailed information on prescribing conditions, please refer to the *Schedule of Pharmaceutical Benefits – Efficient Funding of Chemotherapy*.