Australian Government
Services Australia

medicare

PBS

Metastatic HER2 positive breast cancer – lapatinib – initial authority application

Online services

Requesting PBS Authorities online provides an immediate assessment in real time.

For more information and how to access the **Online PBS Authorities** system, go to **servicesaustralia.gov.au/hppbsauthorities**

When to use this form

Use this form to apply for **initial** PBS-subsidised lapatinib for patients with metastatic (Stage IV) human epidermal growth factor receptor 2 (HER2) positive breast cancer.

Important information

Initial applications to start PBS-subsidised treatment can be made in real time using the **Online PBS Authorities** system or in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

Under no circumstances will phone approvals be granted for metastatic HER2 positive breast cancer **initial** authority applications.

The information in this form is correct at the time of publishing and may be subject to change.

Continuing treatment

This form is ONLY for **initial** treatment.

After an authority application for **initial** treatment has been approved, applications for **continuing** treatment with lapatinib are **Authority Required (STREAMLINED)** and do not require prior authority approval from Services Australia for the listed quantity and repeats.

For more information

Go to **servicesaustralia.gov.au/healthprofessionals**

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Online services

You do not need to complete this form if you use the **Online PBS Authorities** system.

Go to **servicesaustralia.gov.au/hppbsauthorities**

Patient's details

1 Medicare card number

Ref no.

or

Department of Veterans' Affairs card number

2 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

Family name

First given name

3 Date of birth (DD MM YYYY)

4 Patient's weight

kg

Prescriber's details

5 Prescriber number

6 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

Family name

First given name

7 Business phone number (including area code)

Alternative phone number (including area code)

Conditions and criteria

To qualify for PBS authority approval, the following conditions must be met.

8 Does the patient have evidence of HER2 gene amplification, demonstrated by in situ hybridisation (ISH) in the primary tumour or a metastatic lesion confirmed by a pathology report from an Approved Pathology Authority?

No ☐

Yes ☐ Date of the pathology report (DD MM YYYY)

Unique identifying number/code or provider number

9 Does the patient have a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure?

No ☐

Yes ☐

10 Is the patient receiving treatment in combination with capecitabine?

No ☐

Yes ☐

11 Is this treatment the sole PBS-subsidised anti-HER2 therapy for this condition?

No ☐

Yes ☐

MCA0PB099 2409

12 The patient has:

☐ received prior therapy with a taxane for at least 3 cycles and experienced disease progression **during** or **within 6 months** of completing treatment with pertuzumab and trastuzumab in combination

▶ Provide details below

Date of last treatment with a taxane (DD MM YYYY)

Total number of taxane treatment cycles

Dates of treatment with pertuzumab and trastuzumab

From (DD MM YYYY)

To (DD MM YYYY)

Date of disease progression **during** or **within 6 months** pertuzumab and trastuzumab (DD MM YYYY)

or

☐ developed intolerance to treatment with a taxane of a severity necessitating permanent treatment withdrawal and experienced disease progression **during** or **within 6 months** of completing treatment with pertuzumab and trastuzumab in combination

▶ Provide details below

Date of last treatment with a taxane (DD MM YYYY)

Total number of taxane treatment cycles

Dates of treatment with pertuzumab and trastuzumab

From (DD MM YYYY)

To (DD MM YYYY)

Date of disease progression **during** or **within 6 months** pertuzumab and trastuzumab (DD MM YYYY)

If applicable, provide details of intolerance to taxane treatment necessitating permanent treatment withdrawal, including degree of severity and toxicity

or

☐ experienced disease progression following treatment with trastuzumab emtansine in whom disease had relapsed **during** or **within 6 months** of completing prior adjuvant therapy with trastuzumab

▶ Provide details below

Dates of treatment with trastuzumab

From (DD MM YYYY)

To (DD MM YYYY)

Date of relapse **during** or **within 6 months** of trastuzumab (DD MM YYYY)

or

☐ experienced disease relapse **during** or **within 6 months** of completing prior adjuvant therapy with trastuzumab

▶ Provide details below

Dates of treatment with trastuzumab

From (DD MM YYYY)

To (DD MM YYYY)

Date of relapse **during** or **within 6 months** of trastuzumab (DD MM YYYY)

Checklist

13 The relevant attachments need to be provided with this form.

☐ Details of the proposed prescription(s).

Privacy notice

14 Personal information is protected by law (including the *Privacy Act 1988*) and is collected by Services Australia for the purposes of assessing and processing this authority application.

Personal information may be used by Services Australia, or given to other parties where the individual has agreed to this, or where it is required or authorised by law (including for the purpose of research or conducting investigations).

More information about the way in which Services Australia manages personal information, including our privacy policy, can be found at **servicesaustralia.gov.au/privacypolicy**

Prescriber's declaration

You do not need to **sign** the declaration if you complete this form using Adobe Acrobat Reader and return this form through Health Professional Online Services (HPOS) at **servicesaustralia.gov.au/hpos**

15 I declare that:

- I am aware that this patient must meet the criteria listed in the current Schedule of Pharmaceutical Benefits to be eligible for this medicine.
- I have informed the patient that their personal information (including health information) will be disclosed to Services Australia for the purposes of assessing and processing this authority application.
- I have provided details of the proposed prescription(s) and the relevant attachments as specified in the Pharmaceutical Benefits Scheme restriction.
- the information I have provided in this form is complete and correct.

I understand that:

- giving false or misleading information is a serious offence.

☐ I have read, understood and agree to the above.

Date (DD MM YYYY) (you **must** date this declaration)

Prescriber's signature (**only** required if returning by post)

If returning by post, print and sign by hand.

Returning this form

Return this form, details of the proposed prescription(s) and any relevant attachments:

- **online** (no signature required), upload through HPOS at **servicesaustralia.gov.au/hpos**

  or

- by post (signature required) to

  Services Australia
  Complex Drugs Programs
  Reply Paid 9826
  HOBART TAS 7001

Reset form