



# Late stage metastatic breast cancer Initial PBS authority application Supporting information

## Important information

You must lodge this form for a patient starting **initial** PBS subsidised treatment with lapatinib for late stage metastatic breast cancer where disease has progressed despite treatment with trastuzumab.

Lapatinib is not PBS subsidised when used in combination with Commonwealth subsidised trastuzumab.

A pathology report demonstrating that the patient is HER2 positive as demonstrated by In-Situ Hybridisation (ISH) must be submitted with the application.

Lapatinib should not be used in patients with a Left Ventricular Ejection Fraction (LVEF) of less than 45 per cent or with symptomatic heart failure. Cardiac function must be tested by a suitable method, for example, Echocardiogram (ECHO) or Multiple Gated Acquisition scan (MUGA) at three monthly intervals during treatment.

If disease progression occurs, the prescriber must contact Medicare Australia within one week and lapatinib treatment must stop immediately.

All applications must be in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

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

## Acknowledgements

The patient's and the prescriber's acknowledgements must be signed in the presence of a witness (over 18 years of age).

## Authority prescription form

A completed authority prescription form must be attached to this form.

The medical indication section of the authority prescription form does not need to be completed when submitted with this form.

## Phone approvals

Under no circumstance will phone approvals be granted for complete authority applications, or for treatment that would otherwise extend the treatment period.

## Applications for continuing treatment

The assessment of the patient's response to an initial course of treatment should be made after approximately two months of treatment so there is adequate time for a response to be demonstrated. A maximum of three months of treatment will be approved under this criterion.

## Assistance

If you need assistance completing this form, or more information call **1800 700 270** and select option 1 between 8.00 am and 5.00 pm EST Monday to Friday, or go to [www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au) > For health professionals > PBS > Specialised drugs (PBS) J-Z > Late stage metastatic breast cancer

## Lodgement

Send the completed authority application form, all relevant attachments and a completed authority prescription form to:

**Medicare Australia**  
**Prior written approval of specialised drugs**  
**Reply Paid 9826**  
**HOBART TAS 7001**

Print in **BLOCK LETTERS**

Tick where applicable



## Late stage metastatic breast cancer Initial PBS authority application

### Patient's details

**1** Medicare/DVA number  
 -  -  Ref no.

**2** Mr  Mrs  Miss  Ms  Other   
 Family name  
  
 First given name

**3** Date of birth  
 /  /

### Patient's acknowledgement

**4** I acknowledge that PBS subsidised treatment with lapatinib for late stage HER2 positive metastatic breast cancer will stop if:

- subsequent testing demonstrates the disease has progressed.

My prescriber has explained the nature of the ongoing monitoring and testing required to demonstrate an adequate response to treatment.

Patient's signature

Date  
 /  /

### Prescriber's details

**5** Prescriber number

**6** Family name  
  
 First given name

**7** Work phone number  
 ( )   
 Alternative phone number  
  
 Fax number  
 ( )

### Prescriber's declaration and acknowledgement

**8** I declare that I have explained to the patient:

- the circumstances governing PBS subsidised treatment with lapatinib for late stage HER2 positive metastatic breast cancer
- the nature of the ongoing monitoring and testing required to demonstrate the disease has not progressed.

**I acknowledge that:**

- if disease progression occurs I will contact Medicare Australia within one week and stop lapatinib treatment immediately.

I believe these to be understood and accepted by the patient.

Prescriber's signature

Date  
 /  /

### Witness's acknowledgement

**9** I have witnessed the signatures of **BOTH** the patient and the prescriber.

Witness's full name (over 18 years of age)

Witness's signature

Date  
 /  /

## Conditions and criteria

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

### 10 The patient:

has signed the patient acknowledgement

and

is HER2 positive as demonstrated by ISH

and

will be treated in combination with capecitabine

and

has been diagnosed with metastatic breast cancer equivalent to either:

Stage IIIC

or

Stage IV

and

has completed prior therapy for at least three cycles with a taxane

name of taxane

date of last treatment

number of cycles

Provide details of contraindication or intolerance to taxane therapy, including the degree of toxicity.

Details of the toxicity criteria are available at

**[www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au) > For health professionals > PBS > Specialised drugs (PBS) J-Z > Late stage metastatic breast cancer**

Intolerance must be of a severity to necessitate permanent treatment withdrawal.


and

has demonstrated disease progression while on treatment with trastuzumab for metastatic disease.

Provide dates of treatment with trastuzumab (must be for a minimum of six weeks)

from  /  /  to  /  /

Provide date of demonstration of disease progression.

## Attachments



Attach ISH pathology report and completed authority prescription form.

## Prescriber's declaration

### 11 I declare that:

- the information provided on this form is correct.

Prescriber's signature

Date

## Privacy note

The information provided on this form will be used to assess eligibility of a nominated person to receive PBS subsidised treatment. The collection of this information is authorised by the *National Health Act 1953*. This information may be disclosed to the Department of Health and Ageing, Department of Veterans' Affairs or as authorised or required by law.