

Solid tumours with confirmed NTRK gene fusion – larotrectinib – initial authority application

Online PBS Authorities



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 larotrectinib for patients with solid tumours with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion.

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 solid tumours with confirmed NTRK gene fusion **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 can be made in real time using the **Online PBS Authorities** system or by phone. Call 1800 700 270 Monday to Friday, 8 am to 5 pm, local time.

For more information

Go to servicesaustralia.gov.au/healthprofessionals

Solid tumours with confirmed NTRK gene fusion – larotrectinib – initial authority application

Online PBS Authorities



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 Family name

First given name

3 Date of birth (DD MM YYYY)

Prescriber's details

4 Prescriber number

5 Family name

First given name

6 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.

At treatment initiation with this drug, the patient:

- is/was under 18 years **▶ Go to 7**
- is 18 years or over
 - with salivary gland or secretory breast carcinoma **▶ Go to 7**
 - with non-small cell lung cancer, soft tissue sarcoma or either glioma/glioneuronal tumour/glioblastoma **▶ Go to 16**

7 Prior to initiating treatment with this drug, was the condition confirmed to be positive for a NTRK gene fusion through a report (of any date) from an Approved Pathology Authority?

No ☐

Yes ☐

8 Provide details of the pathology report substantiating the positive NTRK gene fusion

Name of the pathology service provider

Date of the pathology report (DD MM YYYY)

Unique identifying number/code

9 The patient's condition is:

☐ metastatic disease

or

☐ locally advanced and unresectable

or

☐ locally advanced and requires disfiguring surgery/limb amputation to achieve complete surgical resection.

10 Is this treatment the sole PBS-subsidised anti-cancer therapy for this condition?

No ☐

Yes ☐



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11 Is the patient undergoing initial PBS-subsidised treatment where disease progression has occurred while previously receiving this drug for this condition?

No ☐

Yes ☐

12 At treatment initiation with this drug, the patient:

☐ is/was under 18 years

► **Go to 26**

or

☐ is 18 years or over

13 The patient's condition, confirmed through a pathology report (of any date) from an Approved Pathology Authority, is:

☐ a mammary analogue secretory carcinoma of the salivary gland

or

☐ a secretory breast carcinoma

14 The pathology report establishing the carcinoma type is:

☐ **different** to the pathology report provided previously to substantiate the NTRK gene fusion

► **Go to 15**

or

☐ the **same** as the pathology report provided previously to substantiate the NTRK gene fusion

► **Go to 26**

15 Provide details of the pathology report confirming the carcinoma type

Name of the pathology service provider

Date of the pathology report (DD MM YYYY)

Unique identifying number/code

► **Go to 26**

For a patient 18 years or over with non-small cell lung cancer, soft tissue sarcoma, or either glioma/glioneuronal tumour/glioblastoma

16 Prior to initiating treatment with this drug, was the condition confirmed to be positive for a NTRK gene fusion through a report (of any date) from an Approved Pathology Authority?

No ☐

Yes ☐

17 Provide details of the pathology report substantiating the positive NTRK gene fusion

Name of the pathology service provider

Date of the pathology report (DD MM YYYY)

Unique identifying number/code

18 The patient's condition is:

☐ metastatic disease

or

☐ locally advanced and unresectable

or

☐ locally advanced where surgical resection is likely to result in severe morbidity.

19 The patient's condition, confirmed through a pathology report (of any date) from an Approved Pathology Authority, is:

☐ non-small cell lung cancer

or

☐ soft tissue sarcoma

or

☐ glioma

or

☐ glioneuronal tumour

or

☐ glioblastoma.

20 The pathology report establishing the carcinoma type is:

☐ **different** to the pathology report provided previously to substantiate the NTRK gene fusion

► **Go to 21**

or

☐ the **same** as the pathology report provided previously to substantiate the NTRK gene fusion

► **Go to 22**

21 Provide details of the pathology report confirming the carcinoma type

Name of the pathology service provider

Date of the pathology report (DD MM YYYY)

Unique identifying number/code

22 The patient has:

☐ received prior systemic treatment for this disease

Provide details of prior systemic treatment

or

☐ a condition that predisposes them to an unacceptable risk of intolerance to other systemic therapies

Provide details of this condition

23 Is this treatment the sole PBS-subsidised anti-cancer therapy for this condition?

No ☐

Yes ☐

24 Is the patient undergoing initial PBS-subsidised treatment where disease progression has occurred while previously receiving this drug for this condition?

No ☐

Yes ☐

25 Will the patient receive more than 3 months of treatment under this restriction?

No ☐

Yes ☐

Checklist

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

☐ Details of the proposed prescription(s).

Privacy notice

27 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

28 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)

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