Lenvima® On-Label Cost-share Program Application

Eisai New Zealand Limited does not seek to profit from the compassionate supply of Eisai medicines, and as such will provide requested medication at a discounted price to support patients who have been prescribed these medicines in settings where they are not currently reimbursed in New Zealand.

Lenvima is provided at a cost of NZD$1,550 excluding GST per box (regardless of strength) to a maximum total cost of NZD$27,900 excluding GST per patient (equivalent to 18 boxes). After this amount is reached, Eisai will continue to provide Lenvima to the patient at no charge contingent on the patient continuing to derive clinical benefit as instructed by the treating oncologist or physician.

Eisai will not compensate for any activities, cost of fees (including pharmacy fees) associated with the use of Lenvima or treatment of the patient.

Please note that Lenvima is Medsafe registered for the treatment of patients with progressive, locally advanced or metastatic, radioactive iodine refractory differentiated thyroid cancer (DTC) AND in combination with pembrolizumab for patients with advanced endometrial carcinoma (EC) who have disease progression following prior systemic therapy in any setting AND in combination with pembrolizumab for the first-line treatment of patients with advanced renal cell carcinoma (RCC) AND in combination with everolimus for the treatment of adult patients with advanced renal cell carcinoma (RCC) whose disease has progressed following one prior vascular endothelial growth factor targeted therapy AND for the first line treatment of unresectable Hepatocellular Carcinoma (HCC).

Please complete the following patient details and physician's declaration to request a cost-share compassionate supply.

SECTION 1. PATIENT DETAILS

Patient Initials (PLEASE USE BLOCK CAPITALS): _____

Patient Year of Birth: _____

Please confirm the cancer type for which supply is sought (tick box):

Treatment of patients with progressive, locally advanced or metastatic, radioactive iodine refractory differentiated thyroid cancer (DTC) ☐
The recommended dose of Lenvima is 24 mg once daily. Treatment should continue as long as there is clinical benefit or until unacceptable toxicity occurs.

Previously treated patients with advanced Endometrial Carcinoma (EC) ☐
Starting dose of 20 mg Lenvima orally once daily in combination with pembrolizumab 200 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.

First-line treatment of patients with advanced Renal Cell Carcinoma (RCC) ☐
Starting dose of 20 mg Lenvima orally once daily in combination with pembrolizumab 200 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.

Previously treated patients with advanced Renal Cell Carcinoma (RCC) ☐
Starting dose of 18 mg Lenvima once daily in combination with 5 mg everolimus once daily. Treatment should continue as long as there is clinical benefit or until unacceptable toxicity occurs.

First-line treatment of Hepatocellular Carcinoma (HCC) ☐
Starting dose in HCC is based on actual body weight:

- 8 mg orally once daily for patients with a body weight of <60 kg or
- 12 mg orally once daily for patients with a body weight of ≥60 kg

Treatment should continue as long as there is clinical benefit or until unacceptable toxicity occurs.

SECTION 2. ORDER AND DELIVERY INFORMATION

Please tick the requested starting daily dose of Lenvima:

Please ensure the dose and quantity is selected carefully as after dispatch, the drug cannot be returned or orders refunded. Prices shown are excluding GST.

☐	**24 mg** (2x 10 mg pack; 1x 4 mg packs)	$4650/month (exl. GST)
☐	**20 mg** (2x 10 mg pack)	$3100/month (exl. GST)
☐	**18 mg** (1 x 10 mg pack; 2 x 4 mg packs)	$4650/month (exl. GST)
☐	**14 mg** (1x 10 mg pack; 1 x 4 mg pack)	$3100/month (exl. GST)
☐	**12 mg** (3 x 4 mg pack)	$4650/month (exl. GST)
☐	**10 mg** (1x 10 mg pack)	$1550/month (exl. GST)
☐	**8 mg** (2 x 4 mg pack)	$3100/month (exl. GST)
☐	**4 mg** (1x 4 mg pack)	$1550/month (exl. GST)

If a selection outside of the recommended Lenvima starting dose is selected, please specify reason below (TICK BOX):

☐ Severe hepatic impairment
☐ Severe renal impairment
☐ Other (please specify):

_____

PLEASE NOTE: Starting doses which differ from the recommended starting dose of the Lenvima Data Sheet will be reported to Pharmacovigilance.

The delivery will occur in ≤ 5 business days after receipt of order and delivery costs will be absorbed by Eisai. For any urgent overnight or same day deliveries, Eisai will be required to on-charge a courier fee (determined by location).

Delivery Details (PLEASE USE BLOCK CAPITALS)

Pharmacist Name (Title, Full First Name, Full Family Name):

_____

Contact Telephone Number: _____

Email Address: _____

Delivery Address

Name hospital/pharmacy: _____

Number and street for drug deliveries: _____

_____

City: _____

Post Code: _____

SECTION 3: PHYSICIANS DECLARATION

1. I acknowledge that the use of Lenvima remains the clinical decision of the prescriber.

2. I confirm that I accept full legal liability and responsibility for the use of Lenvima for the patient named in this application who is under my care. Subject to its obligations under New Zealand law and the New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods, I understand that Eisai New Zealand Ltd, together with its affiliates, subsidiaries, parent and their respective employees, directors and officers ("Eisai") will not indemnify or compensate me (or any person or local facility that I use to treat the named patient) for any injuries or adverse effects relating to the use of Lenvima.

3. All information disclosed within the context of this cost-share patient program shall be treated as confidential by me and shall only be used for the purpose of the Lenvima supply to, and the clinical care of, the named patient.

4. I acknowledge and agree to Eisai and its logistics provider currently Healthcare Logistics (HCL), and any other service providers of Eisai:

    a) Collecting certain personal data in this form including my name, telephone number, address, email address and physician registration/licence number.

    b) Processing my personal data for Eisai to:
        i. obtain an overview of participation, activity and safety reporting in the program;
        ii. comply with Eisai's safety reporting obligations; and
        iii. provide Lenvima to the named patient and to manage the program,

    and as otherwise required by law and/or Eisai's internal business processes, including in relation to accounting and records requirements.

    c) Processing my personal data to perform statistical analysis, including to analyse participation levels in relation to the program and produce related reports, and to send communications to me which are related to the administration of this program.

5. I acknowledge and agree that:
    a) if I do not provide all of the personal data that may be requested, Eisai may be unable to provide the named patient with access to the cost-share program.

    b) Eisai may disclose my personal data to third parties including service providers, affiliates of Eisai and to governmental, tax or regulatory authorities and other third parties as required or permitted by law. Eisai will take steps to ensure that my personal data is protected, however my personal data may be held on databases in countries outside of New Zealand, including within the European Economic Area and the United States, which may not have data protection laws equivalent to those in New Zealand. In such a case, the necessary measures will be taken by Eisai to ensure the safety of my personal data in accordance with applicable data protection laws in those countries.

    c) Under applicable data protection laws, I may have the right to request access to my personal data and to request the correction of any error in relation to my personal data. If I wish to exercise these access or correction rights, or have any questions or comments concerning the use of my personal data, I may contact Eisai at medinfo_newzealand@eisai.net.

    d) When I request that the personal data that Eisai holds about me be corrected, I may also provide Eisai with a statement of correction being sought and if the requested correction is not made, I may request that the statement of correction be attached to the information that I have asked to be corrected so that it is read with my personal data.

6. By signing this form, I consent to my personal data being used, and authorise the cross-border disclosure of my personal data, as described in paragraphs 4 and 55.a of this physician's declaration. For more information about Eisai's privacy practices, please read the privacy policy at: https://www.eisai.co.nz/privacy-policy/. To the extent that any terms of this application are inconsistent with the privacy policy, the terms of this application will take precedence.

7. I have requested supply of Lenvima for the named patient under a cost-share based agreement. I have informed the patient (including the patient's parent/legal guardian if required) that s/he is consenting to treatment with Lenvima and s/he understands whether Lenvima is, or is not, currently approved in New Zealand for this indication for which the medication has been requested according to local laws.

8. I have informed the patient (including the patient's parent/legal guardian if required) that the personal data, including sensitive personal data such as health data, collected about him/her in relation to the supply of Lenvima may be provided to Eisai in order for Eisai to provide Lenvima to the patient, obtain an overview on participation, activity and safety reporting in the program and, in respect of certain limited personal data, for HCL or any other relevant service provider to comply with its own safety reporting obligations.

9. I have informed the patient that his/her personal data including sensitive personal data may be reported to regulatory authorities if required by law. The patient (including the patient's parent/legal guardian if required) is informed that his/her personal data may be disclosed to third parties that may be located in countries outside of New Zealand including the United States, which may not have data protection laws equivalent to those in New Zealand and that in such a case, the necessary measures will be taken by Eisai to ensure the safety of his/her personal data in accordance with applicable data protection laws. I confirm that the patient (including the patient's parent/legal guardian if required) has explicitly consented to the disclosure of his/her personal data to Eisai (and Eisai's service providers), and to the use, processing and cross-border disclosure of his/her personal data as described above in paragraph 8 and this paragraph 9.

10. I confirm that the requested Lenvima supplies are only for the named patient above and will not be used for other purposes. All unused or expired blister packs of Lenvima will be destroyed according to local procedures.

11. I have received, read and understood the Data Sheet provided by Eisai and understand and agree to comply with the specific storage, safety and administration requirements for Lenvima. I will keep Lenvima in a locked, secure area at all times and shall maintain complete records for receipt, dispensing and returns or destruction of Lenvima in accordance with all applicable laws, regulations and guidelines. I also agree to take all reasonable precautions against destruction, theft or other loss of the drug. I also agree to use the Lenvima provided by Eisai solely for the named patient and in accordance with all requirements imposed by local health and regulatory authorities.
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12. I understand that it is my responsibility to report to Eisai all adverse events that occur while the patient is being treated with this medication. All suspected adverse events (both serious and non-serious) must be reported immediately to safety_newzealand@eisai.net or +61 3 9832 9100. I agree that by participating in this cost-share program, I will be contacted for follow up of any adverse events that have been reported.

13. I understand that Eisai will not compensate me (or any person or local facility that I use to treat the named patient) for any activities, costs or fees (including pharmacy fees) associated with the use of Lenvima or treatment of the patient.

14. I declare that I am a practicing physician in good standing with my medical licensing board, and I have deemed it appropriate, based on my independent medical judgment, medical evaluation of this patient and this patient's current medical condition and history, to treat the named patient with Lenvima.

Treating Physician Details (PLEASE USE BLOCK CAPITALS)

Name: (TITLE, FULL FIRST NAME & FAMILY NAME):

_____

Contact Telephone Number:

_____

Practice Address:

_____

Email Address:

_____

Medical Council of New Zealand Registration Number:

_____

Treating Physicians Signature: _____ Date: _____

Please scan and return this form to Eisai New Zealand at medicalaccess_nz@eisai.net

If you have any questions please do not hesitate to contact Eisai New Zealand Ltd at the above email or contact Lynda Johnston on +64 276 700 221.

Lenvima® (lenvatinib mesilate) – Prescription Medicine, unfunded (prescription charge will apply). Before prescribing Lenvima review the Data Sheet for information on dosage, contraindications, precautions, interactions and adverse effects, available at www.medsafe.govt.nz. Lenvima is a registered trademark of the Eisai Group whose affiliate company in New Zealand is Eisai New Zealand Limited, c/o Simpson Grierson, Level 27, 88 Shortland Street, Auckland Central, Auckland, 1010. Eisai Australia & New Zealand. Medical Information: +613 9832 9100 or medinfo_newzealand@eisai.net. NZ-LENB-23-00004. TAPS DA 2334MR.