

APPLICATION FORM FOR LEVETIRACETAM SPECIAL ACCESS

Return completed form to:

The Coordinator
Levetiracetam Special Access Panel
PHARMAC PO Box 10 254
Wellington
Phone: 04 916-7553
Facsimile: 09 929-3226
Email: Isacoordinator@pharmac.govt.nz

New Zealand Government

PHARMAC
Pharmaceutical Management Agency

Applications must be completed by a registered medical practitioner. Applications will be considered by the Levetiracetam Special Access (LSA) Panel at the soonest practicable opportunity. Notification of the decision will be sent to the applying clinician.

Please note:

(a) LSA funding will be approved for the Keppra brand of levetiracetam only. PHARMAC has not entered into a listing contract with the supplier of Keppra. Therefore, for approved applications there is no surety of source of, or ongoing supply of, levetiracetam.

(b) Approved applications will remain valid until expiry or until such time as an agreed ongoing supply of levetiracetam is available through the Pharmaceutical Schedule. After that time, neither new approvals nor renewals will be given. In order to continue to receive subsidised levetiracetam patients with existing approvals would need to use a Pharmaceutical Schedule listed brand. Any applicant who considered that their patient should remain on the Keppra brand (if not listed in the Schedule) would need to apply in writing outlining the reasons why (at a minimum, patients must have been seizure free for at least 6 months for ongoing Keppra subsidy to be considered).

1. GENERAL INFORMATION

Details of Applying Practitioner (stamp or sticker acceptable)

Last name: _____

First name: _____

Address: _____

Phone: _____

Facsimile: _____

NZMC #: _____

Email: _____

Patient Details

Last name: _____

First name: _____

Gender: Male Female

Date of Birth: _____

NHI #: _____

Details of Levetiracetam (please ensure that all fields, including the anticipated cost, are completed)

Brand name: Keppra (note that no other brand of levetiracetam will be subsidised under LSA)

Manufacturer: UCB Pharma

Form and Strength: _____

Dosage to be used: _____

Anticipated cost per month quoted by nominated pharmacy*: _____

* please do not include pharmacy markup in this quote, as pharmacy markups will not be reimbursed for levetiracetam funded through LSA. Pharmacies will, however, receive 1.5x the standard dispensing fee.

Details of Nominated Pharmacy (name of pharmacy where the patient will have Keppra dispensed)

Name: _____

Address: _____

2. INITIAL APPLICATION (do not complete for renewal applications)

Approvals valid for 6 months.

(a) Applications will be considered for patients meeting the following criteria:

- Patient has been diagnosed with epilepsy. Please specify type of epilepsy (if known) _____

and

- All currently subsidised antiepilepsy agents have been given a reasonable trial or are contraindicated or unsuitable (details of treatment to be provided by applicant). A reasonable trial is defined as treatment with subsidised antiepilepsy agents, given alone or in combination, which are indicated and clinically appropriate for the patient, given in adequate doses for the patient's age, weight, and other features affecting the pharmacokinetics of the drug with good evidence of compliance;

and

- Seizures are not adequately controlled with currently subsidised antiepilepsy agents;

or

- Seizures are controlled adequately but the patient has experienced unacceptable side effects from currently funded antiepilepsy agents;

and

- Details of the patient's treatment history are attached, including details of subsidised pharmaceuticals that have been trialed or considered. Please ensure that this information is provided in relation to the following pharmaceuticals (including details of combination treatments trialed): carbamazepine, clobazam, clonazepam, ethosuximide, gabapentin, lamotrigine, phenobarbitone, phenytoin sodium, primidone, sodium valproate, topiramate, vigabatrin. Note that a trial of all these pharmaceuticals is not a prerequisite, but if a pharmaceutical has not been trialed the reason must be provided.

(b) Applicants are also encouraged to provide any additional information that may be relevant:

- An opinion from a(nother) specialist is attached to this application. Please provide contact details of the specialist the patient has seen and who can be contacted by the LSA Panel:

Name of specialist: _____

Phone: _____

Address: _____

(Note: a specialist opinion is not a prerequisite; however, the LSA Panel reserves the right to seek any appropriate opinion)

- Additional relevant information is attached (please briefly state the nature and number of the additional attachments)

3. RENEWAL APPLICATION (complete for renewal applications only)

Approved renewal applications will be valid for 12 months.

(a) Please detail the patient's clinical progress, including details of reduction in seizure frequency from use of levetiracetam, and the need for continued treatment with levetiracetam.

(b) Applicants are also encouraged to provide any additional relevant information that may be relevant:

An opinion from a(nother) specialist is attached to this application. Please provide contact details of the specialist the patient has seen and who can be contacted by the LSA Panel:

Name of specialist: _____

Address: _____

Phone: _____

(Note: a specialist opinion is not a prerequisite; however, the LSA Panel reserves the right to seek any appropriate opinion)

Additional relevant information is attached (please briefly state the nature and number of the additional attachments)

4. RE-EVALUATION AND REVIEW PROCEDURE

(a) In the first instance, an application for re-evaluation of the decision is to be referred directly to the LSA Panel Coordinator. The LSA Panel is to consider that application for re-evaluation within a reasonable time and is to provide a summary of that application for re-evaluation to PHARMAC. The LSA Panel is to provide PHARMAC with such further details in relation to any such application for re-evaluation as it may reasonably request.

(b) If after considering an application for re-evaluation under paragraph (a), above, the LSA Panel upholds its recommendation not to grant the applicant subsidised access to levetiracetam, then the applicant may request a review. Contact should be made with PHARMAC's Medical Director, who will arrange for a review to be undertaken.

5. CONSENT BY PATIENT OR GUARDIAN

For the purposes of this application form I consent to:

- information concerning my medical conditions being given to the Levetiracetam Special Access Panel (and if required, to PHARMAC or its auditors); and
- the Levetiracetam Special Access Panel seeking further information from medical care providers or seeking further medical opinion as may be necessary for the consideration of this application.

Signed: _____ Date: _____

6. APPLICANT SIGNATURE

I, the applying practitioner, confirm that the details in this application are correct and that in signing this form I understand I may be audited.

Signature of Applying Practitioner: _____