

23 May 2007

To All Pharmaceutical Suppliers, Medical Groups and Interested Parties

Proposal to replace the Special Authority for New Antiepilepsy Drugs (NAEDs) and to remove the NAED heading from the Pharmaceutical Schedule

There is currently one Special Authority for all New Antiepilepsy Drugs (NAEDs), with restrictions on the number of products for which an approval is valid.

PHARMAC is proposing to replace the Special Authority for NAEDs in Section B of the Pharmaceutical with new Special Authorities – one for each NAED.

PHARMAC is currently progressing a proposal to remove the Special Authority requirement for lamotrigine (Lamictal). If that Lamictal proposal and this current proposal are both approved by PHARMAC's Board, a separate Special Authority would apply to each of topiramate, gabapentin, and vigabatrin (otherwise Lamictal would also have a separate Special Authority). Current approvals under the existing NAED Special Authority would continue to be valid for any of the affected products (i.e. no new Special Authorities would be required for existing patients other than a renewal requirement).

At the same time, PHARMAC is proposing to remove the "New Antiepilepsy Drugs" subheading from Section B of the Pharmaceutical Schedule, and list all the relevant agents under the "Control of Epilepsy" section of the Schedule. We are now seeking feedback on this proposal.

Key aspects of this proposal are as follows:

- The current Special Authority for subsidy of New Antiepilepsy Drugs would be replaced by new Special Authorities for gabapentin, topiramate and vigabatrin (and possibly Lamictal depending on the outcome of a separate proposal) as detailed in an attachment to this letter. Copies of the proposed new Special Authority forms are also attached.
- For patients with current Special Authority approvals for treatment of epilepsy, the current Special Authority would be linked to all new Special Authorities, which means that patients with an existing approved Special Authority (either initial or renewal) would automatically be considered to have an approved initial application for all of the new Special Authorities. Current approved Special Authorities for gabapentin for neuropathic pain would only be linked to the new gabapentin Special Authority. Current expiry dates would transfer to the new approvals.
- At the expiry of an existing approved Special Authority, prescribers would need to apply for renewals of the Special Authority for each individual agent. However, under this proposal all renewals except those for gabapentin for neuropathic pain would be valid without further renewal.
- If a prescriber wished to prescribe gabapentin, vigabatrin and/or topiramate (and possibly Lamictal, see above) for a patient who does not have an existing approved Special Authority, a new application would be needed for each individual pharmaceutical.

- The specialist restrictions would be removed from the new Special Authorities, such that Special Authority applications could be made by any relevant practitioner.
- The “New Antiepilepsy Drugs” subheading would be removed from Section B of the Pharmaceutical Schedule, and all the relevant agents would be listed under the “Control of Epilepsy” section of the Schedule.
- It is proposed that these changes would take effect from 1 August 2007.

If you wish to make comments for the PHARMAC Board to consider when making its decision on whether to accept this proposal, please forward them to PHARMAC by **5:00 pm, 8 June 2007**. All comments submitted by this date will be considered.

Yours sincerely



Geraldine MacGibbon
Therapeutic Group Manager

Appendix: Further details of proposed changes

PHARMAC proposes that the existing Special Authority would be deleted and existing approvals linked to all three new Special Authority forms, as follows:

1. Current Special Authority form

The existing Special Authority, as shown below, would be deleted

SA0780 Special Authority for Subsidy

Initial application - (Single NAED Therapy) only from a paediatrician, neurologist or general physician. Approvals valid for 15 months for applications meeting the following criteria:

Any of the following:

- 1 Was on NAED therapy before 1 September 2000; or
- 2 Seizures are not adequately controlled with optimal older antiepilepsy drug treatment; or
- 3 Seizures are controlled adequately but who experience unacceptable side effects from older anti-epilepsy drug treatment.

Note: "Optimal older anti-epilepsy drug therapy" is defined as treatment with those older anti-epilepsy drugs which are indicated and clinically appropriate for the patient, given singly and in combination in adequate doses for the patient's age, weight, and other features affecting the pharmacokinetics of the drug with good evidence of compliance.

Initial application - (Dual NAED Therapy) only from a paediatrician, neurologist or general physician. Approvals valid for 18 months for applications meeting the following criteria:

Either:

- 1 Stabilised on two NAEDs on or before 31 July 2000; or
- 2 Both:
 - 2.1 A second NAED has been added; and
 - 2.2 An attempt to withdraw one NAED has been made and was unsuccessful.

Initial application - (Neuropathic pain - gabapentin only) only from a relevant specialist, vocationally registered general practitioner or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 months where the patient has tried and failed, or has been unable to tolerate, treatment with a tricyclic antidepressant AND an anticonvulsant agent.

Notes: Gabapentin is not interchangeable with other NAEDs when used for treating neuropathic pain.

Vocationally registered general practitioners are a relevant specialist when recommending gabapentin for neuropathic pain.

Renewal - (Single or Dual NAED Therapy) only from a paediatrician, neurologist or general physician. Approvals valid for 18 months for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 Patient has been prescribed adequate doses of gabapentin, lamotrigine, topiramate or vigabatrin; and
 - 1.2 Patient has demonstrated a significant and sustained improvement in seizure rate or severity and/or quality of life; or
- 2 Patient has had a previous approval but has not yet trialed monotherapy with all available NAEDs.

Note: As a guideline, clinical trials have referred to a notional 50% reduction in seizure frequency as an indicator of success with anti-convulsant therapy and have assessed quality of life from the patient's perspective.

Renewal - (Triple NAED Therapy) only from a paediatrician, neurologist or general physician. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient is on dual therapy; and
- 2 Patient switching from vigabatrin to another NAED.

Renewal - (Neuropathic pain - gabapentin only) only from a relevant specialist, vocationally registered general practitioner or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years where the patient has demonstrated a marked improvement in their control of pain (prescriber determined).

Notes: Gabapentin is not interchangeable with other NAEDs when used for treating neuropathic pain.

Vocationally registered general practitioners are a relevant specialist when recommending gabapentin for neuropathic pain

Note: Special Authority applications and reapplications for NAEDs (for use in epilepsy) must be made by a neurologist or paediatric neurologist. Applications from a general physician or paediatrician will be accepted if access to neurology or paediatric neurology services is limited in the locality in which they practice.

2. Gabapentin

A new Special Authority restriction would apply to gabapentin for patients with epilepsy and/or neuropathic pain, as follows:

Sxxxx Special Authority for Subsidy

Initial application - (Epilepsy) from any relevant practitioner. Approvals valid for 15 months for applications meeting the following criteria:

Either:

- 1 Seizures are not adequately controlled with optimal treatment with other antiepilepsy agents; or
- 2 Seizures are controlled adequately but the patient has experienced unacceptable side effects from optimal treatment with other antiepilepsy agents.

Note: "Optimal treatment with other antiepilepsy agents" is defined as treatment with other antiepilepsy agents 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.

Initial application - (Neuropathic pain) from any relevant practitioner. Approvals valid for 3 months where the patient has tried and failed, or has been unable to tolerate, treatment with a tricyclic antidepressant AND an anticonvulsant agent.

Renewal - (Epilepsy) from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has demonstrated a significant and sustained improvement in seizure rate or severity and/or quality of life.

Note: As a guideline, clinical trials have referred to a notional 50% reduction in seizure frequency as an indicator of success with anticonvulsant therapy and have assessed quality of life from the patient's perspective.

Renewal - (Neuropathic pain) from any relevant practitioner. Approvals valid for 2 years where the patient has demonstrated a marked improvement in their control of pain (prescriber determined).

3. Topiramate

A new Special Authority restriction would apply to topiramate for patients with epilepsy, as follows:

SAXxxx Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 15 months for applications meeting the following criteria:

Both:

- 1 Patient has epilepsy; and
- 2 Either:
 - 2.1 Seizures are not adequately controlled with optimal treatment with other antiepilepsy agents; or
 - 2.2 Seizures are controlled adequately but the patient has experienced unacceptable side effects from optimal treatment with other antiepilepsy agents.

Note: "Optimal treatment with other antiepilepsy agents" is defined as treatment with other antiepilepsy agents 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.

Renewal from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has demonstrated a significant and sustained improvement in seizure rate or severity and/or quality of life.

Note: As a guideline, clinical trials have referred to a notional 50% reduction in seizure frequency as an indicator of success with anticonvulsant therapy and have assessed quality of life from the patient's perspective.

4. Vigabatrin

A new Special Authority restriction would apply to vigabatrin for patients with epilepsy, as follows:

SAXxxx Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 15 months for applications meeting the following criteria:

All of:

- 1 Patient has epilepsy; and
- 2 Either:
 - 2.1 Seizures are not adequately controlled with optimal treatment with other antiepilepsy agents; or
 - 2.2 Seizures are controlled adequately but the patient has experienced unacceptable side effects from optimal treatment with other antiepilepsy agents; and
- 3 Either:
 - 3.1 Patient is, or will be, receiving regular automated visual field testing (ideally before starting therapy and on a 6-monthly basis thereafter); or
 - 3.2 It is impractical or impossible (due to comorbid conditions) to monitor the patient's visual fields.

Notes: "Optimal treatment with other antiepilepsy agents" is defined as treatment with other antiepilepsy agents 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.

Vigabatrin is associated with a risk of irreversible visual field defects, which may be asymptomatic in the early stages.

Renewal from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- 1 Patient has demonstrated a significant and sustained improvement in seizure rate or severity and/or quality of life; and
- 2 Either:
 - 2.1 Patient is receiving regular automated visual field testing (ideally every 6 months) on an ongoing basis for the duration of treatment with vigabatrin; or
 - 2.2 It is impractical or impossible (due to comorbid conditions) to monitor the patient's visual fields.

Notes: As a guideline, clinical trials have referred to a notional 50% reduction in seizure frequency as an indicator of success with anticonvulsant therapy and have assessed quality of life from the patient's perspective.

Vigabatrin is associated with a risk of irreversible visual field defects, which may be asymptomatic in the early stages.

APPLICANT (stamp or sticker acceptable) **PATIENT NHI:** **REFERRER**

Name: First Names: Name:

Address: Surname: Address:

..... DOB:

..... Address:

Fax Number: Fax Number:

NZMC No: NZMC No:

Gabapentin

INITIAL APPLICATION - Epilepsy

Applications from any relevant practitioner. Approvals valid for 15 months.

Prerequisites (tick boxes where appropriate)

Seizures are not adequately controlled with optimal treatment with other antiepilepsy agents

or

Seizures are controlled adequately but the patient has experienced unacceptable side effects from optimal treatment with other antiepilepsy agents

Note:

"Optimal treatment with other antiepilepsy agents" is defined as treatment with other antiepilepsy agents 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.

INITIAL APPLICATION - Neuropathic pain

Applications from any relevant practitioner. Approvals valid for 3 months.

Prerequisites (tick box where appropriate)

The patient has tried and failed, or has been unable to tolerate, treatment with a tricyclic antidepressant AND an anticonvulsant agent

RENEWAL - Epilepsy

Current approval Number:.....

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

Prerequisites (tick box where appropriate)

The patient has demonstrated a significant and sustained improvement in seizure rate or severity and/or quality of life

Note:

As a guideline, clinical trials have referred to a notional 50% reduction in seizure frequency as an indicator of success with anticonvulsant therapy and have assessed quality of life from the patient's perspective.

RENEWAL - Neuropathic pain

Current approval Number:.....

Applications from any relevant practitioner. Approvals valid for 2 years.

Prerequisites (tick box where appropriate)

The patient has demonstrated a marked improvement in their control of pain (prescriber determined)

I confirm the above details are correct and that in signing this form I understand I may be audited.

Signed: Date:

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

APPLICANT (stamp or sticker acceptable) **PATIENT NHI:** **REFERRER**

Name: First Names: Name:
Address: Surname: Address:
..... DOB:
..... Address:
Fax Number: Fax Number:
NZMC No: NZMC No:

Topiramate

INITIAL APPLICATION

Applications from any relevant practitioner. Approvals valid for 15 months.

Prerequisites (tick boxes where appropriate)

Patient has epilepsy

and

Seizures are not adequately controlled with optimal treatment with other antiepilepsy agents

or

Seizures are controlled adequately but the patient has experienced unacceptable side effects from optimal treatment with other antiepilepsy agents

Note:

“Optimal treatment with other antiepilepsy agents” is defined as treatment with other antiepilepsy agents 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.

RENEWAL

Current approval Number:.....

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

Prerequisites (tick box where appropriate)

The patient has demonstrated a significant and sustained improvement in seizure rate or severity and/or quality of life

Note:

As a guideline, clinical trials have referred to a notional 50% reduction in seizure frequency as an indicator of success with anticonvulsant therapy and have assessed quality of life from the patient’s perspective.

I confirm the above details are correct and that in signing this form I understand I may be audited.

Signed: Date:

Post application to Health Payments, Agreements and Compliance (HealthPAC), Private Bag 3015, Wanganui - Fax: 0800 100 131

APPLICANT (stamp or sticker acceptable) **PATIENT NHI:** **REFERRER**

Name: First Names: Name:

Address: Surname: Address:

..... DOB:

..... Address:

Fax Number: Fax Number:

NZMC No: NZMC No:

Vigabatri

INITIAL APPLICATION

Applications from any relevant practitioner. Approvals valid for 15 months.

Prerequisites (tick boxes where appropriate)

Patient has epilepsy

and

Seizures are not adequately controlled with optimal treatment with other antiepilepsy agents

or
 Seizures are controlled adequately but the patient has experienced unacceptable side effects from optimal treatment with other antiepilepsy agents

and

Patient is, or will be, receiving regular automated visual field testing (ideally before starting therapy and on a 6-monthly basis thereafter)

or
 It is impractical or impossible (due to comorbid conditions) to monitor the patient's visual fields

Note:

"Optimal treatment with other antiepilepsy agents" is defined as treatment with other antiepilepsy agents 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.

Vigabatrin is associated with a risk of irreversible visual field defects, which may be asymptomatic in the early stages.

RENEWAL

Current approval Number:.....

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

Prerequisites (tick boxes where appropriate)

The patient has demonstrated a significant and sustained improvement in seizure rate or severity and/or quality of life

and

Patient is receiving regular automated visual field testing (ideally every 6 months) on an ongoing basis for duration of treatment with vigabatrin

or
 It is impractical or impossible (due to comorbid conditions) to monitor the patient's visual fields

Note:

As a guideline, clinical trials have referred to a notional 50% reduction in seizure frequency as an indicator of success with anticonvulsant therapy and have assessed quality of life from the patient's perspective.

Vigabatrin is associated with a risk of irreversible visual field defects, which may be asymptomatic in the early stages.

I confirm the above details are correct and that in signing this form I understand I may be audited.

Signed: Date: