

29 August 2008

Proposal to amend restrictions on nervous system pharmaceuticals

Proposal summary

PHARMAC is seeking feedback on a proposal to amend restrictions applying to the subsidy for several nervous system pharmaceuticals, with effect from 1 December 2008.

Access to the antiepilepsy treatment vigabatrin would be widened by amending the Special Authority criteria to include the treatment of infantile spasms.

In addition, prescriber-specific restrictions would be removed from the Special Authorities for the antinausea treatments domperidone tablets and hyoscine (scopolamine) patches, and from the listings of the Parkinson's disease treatments pergolide and ropinirole and the antipsychotic clozapine.

We note that while the proposal includes the removal of a prescriber-specific restriction for clozapine, there are strict regulations for the prescribing of this product as required by Medsafe, which are detailed later in this consultation letter.

Further details of the proposal can be found on the following pages.

Feedback sought

We welcome your feedback on this proposal. To provide feedback please submit an email, fax or letter by **4 pm, Monday 15 September 2008** to:

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All feedback received before the closing date will be considered when a decision is made on this proposal by PHARMAC's Board (or Chief Executive under delegated authority).

The details of the proposal

Proposed amendments to the Pharmaceutical Schedule are as follows (deletions shown in strikethrough, additions in bold):

PERGOLIDE —~~Retail pharmacy~~ Specialist

ROPINIROLE HYDROCHLORIDE —~~Retail pharmacy~~ Specialist

CLOZAPINE – Hospital pharmacy [HP4]-~~Specialist prescription~~

We note that in accordance with Medsafe's regulations clozapine may only be prescribed by:

- Registered medical practitioners as defined in the Health Practitioners Competence Assurance Act 2003 who are certified by the Medical Council of New Zealand as competent in the scope of practice of psychiatry, and
- Medical practitioners employed as registrars in the branch of psychiatry who are under the supervision of persons of the kind referred to above, and
- Medical officers of special scale who:
 - work solely in the field of psychiatry;
 - are in the employment of a District Health Board; and
 - are under the supervision of persons who are registered medical practitioners as defined in the Health Practitioners Competence Assurance Act 2003 who are certified by the Medical Council of New Zealand as competent in the scope of practice of psychiatry.

In addition, persons prescribing clozapine must comply with appropriate local treatment guidelines, and clozapine must be dispensed in accordance with appropriate local dispensing guidelines.

VIGABATRIN – Special Authority see SA0875 below – Retail Pharmacy
Tab 500 mg

SA0875 Special Authority for Subsidy

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

Both:

1 Either:

1.1 Patient has infantile spasms; or

1.2 Patient has epilepsy; and

1.2.1 Either:

- 1.2.1.1** Seizures are not adequately controlled with optimal treatment with other antiepilepsy agents; or
- 1.2.1.2** Seizures are controlled adequately but the patient has experienced unacceptable side effects from optimal treatment with other antiepilepsy agents; and

2 Either:

- 2.1** Patient is, or will be, receiving regular automated visual field testing (ideally before starting therapy and on a 6-monthly basis thereafter); or
- 2.2** 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.

Initial application - (patient has had an approval for gabapentin, lamotrigine, topiramate or vigabatrin for epilepsy prior to 1 August 2007) 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 from gabapentin, topiramate, vigabatrin and /or lamotrigine; 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.

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.

If the patient had an approval for gabapentin, lamotrigine, topiramate or vigabatrin for epilepsy prior to 1 August 2007 the applicant is required to submit a fresh initial application in the first instance, not a renewal application.

DOMPERIDONE – Additional subsidy by Special Authority see SA0435 below – Retail Pharmacy

Tab 10 mg

SA0435 Special Authority for Manufacturers Price

Initial application from any ~~medical~~ **relevant** practitioner. Approvals valid for 6 months where the patient is terminally ill and requires control of nausea and vomiting.

Renewal from any ~~medical~~ **relevant** practitioner. Approvals valid for 6 months where the treatment remains appropriate and the patient is benefiting from treatment.

HYOSCINE (SCOPOLAMINE) – Special Authority see SA0727 below – Hospital pharmacy [HP3]

Patches, 1.5 mg

SA0727 Special Authority for Subsidy

Initial application from any ~~medical~~ **relevant** practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 Control of intractable nausea, vomiting, or inability to swallow saliva in the treatment of malignancy or chronic disease; and
- 2 Patient cannot tolerate or does not adequately respond to oral anti-nausea agents; and
- 3 The applicant must specify the underlying malignancy or chronic disease.

Renewal from any ~~medical~~ **relevant** practitioner. Approvals valid for 1 year where the treatment remains appropriate and the patient is benefiting from treatment.