CONSULTATION

PHARMAC
Pharmaceutical Management Agency

7 August 2014

Everolimus (Afinitor)

PHARMAC is proposing to list everolimus (Afinitor) on the Pharmaceutical Schedule for patients with subependymal giant cell astrocytomas.

- Everolimus (Afinitor) would be listed in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 November 2014 at the following prices and subsidies (ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Strength	Pack size	Price and subsidy
Everolimus	Tablet	Afinitor	5 mg	30	$4,555.76
Everolimus	Tablet	Afinitor	10 mg	30	$6,512.29

- A confidential rebate would apply to Afinitor which would reduce the net price of the treatment.
- Afinitor would have subsidy and delisting protection until 31 October 2017.
- Everolimus would be listed subject to the following restrictions in Section B and Part II of Section H of the Pharmaceutical Schedule:

Section B

Special Authority for Subsidy
Initial application only from a neurologist or oncologist. Approvals valid for 3 months for applications meeting the following criteria:
Both:
1. Patient has tuberous sclerosis; and
2. Patient has progressively enlarging sub-ependymal giant cell astrocytomas (SEGAs) that require treatment.

Renewal only from a neurologist or oncologist. Approvals valid for 3 months for applications meeting the following criteria:
Both:
1. Documented evidence of SEGA reduction or stabilisation by MRI within the last 3 months; and
2. The treatment remains appropriate and the patient is benefiting from treatment.

Part II of Section H

Initiation
Neurologist or oncologist
Re-assessment required after 3 months
Both:
1. Patient has tuberous sclerosis; and
2. Patient has progressively enlarging sub-ependymal giant cell astrocytomas (SEGAs) that require treatment.

Continuation
Neurologist or oncologist

Level 9, 40 Mercer Street, PO Box 10-254, Wellington 6143, New Zealand
Phone: 64 4 460 4990 - Fax: 64 4 460 4995 - www.pharmac.govt.nz

Re-assessment required after 3 months
Both:

1. Documented evidence of SEGA reduction or stabilisation by MRI within the last 3 months; and
2. The treatment remains appropriate and the patient is benefiting from treatment.

About everolimus

Everolimus is approved by Medsafe for the treatment of patients aged 3 years and older with sub-ependymal giant cell astrocytomas (SEGAs), a form of brain tumour, associated with tuberous sclerosis complex (TSC) who require therapeutic intervention but are not amenable to surgery.

The listing of everolimus would provide a non-invasive treatment option for patients with progressively enlarging SEGAs.

PTAC and its Cancer Treatments Subcommittee (CaTSoP) and the Neurological Subcommittee of PTAC have each reviewed everolimus for treatment of SEGAs. In May 2014 PTAC accepted the Neurological Subcommittee's November 2013 recommendation to fund everolimus for tuberous sclerosis patients with progressively enlarging SEGAs requiring treatment, with high priority.

The minutes for the relevant reviews can be found on the PHARMAC website through the following link:

- http://www.pharmac.govt.nz/patients/ApplicationTracker?ProposalId=753