

29 July 2010

Proposal to widen access to temozolomide

PHARMAC is seeking feedback on a proposal to widen funded access to temozolomide from 1 October 2010 to include the treatment of patients with newly diagnosed anaplastic astrocytoma.

We also propose to decline other temozolomide funding applications for:

- increasing the number of funded treatment cycles;
- treatment following disease relapse; and
- treatment where surgery and/or radiation is contraindicated.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Thursday, 12 August 2010** to:

Jackie Evans
Therapeutic Group Manager
PHARMAC
PO Box 10 254
Wellington 6143

Email: jackie.evans@pharmac.govt.nz

Fax: 04 460 4995

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

Details of the proposal

The Special Authority criteria applying to the funding of temozolomide would be amended from 1 October 2010 as follows (changes in bold):

Initial application only from a relevant specialist. Approvals valid for 10 months for applications meeting the following criteria:

All of the following:

- 1 Patient has newly diagnosed glioblastoma multiforme **or newly diagnosed anaplastic astrocytoma***; and
- 2 Temozolomide is to be (or has been) given concomitantly with radiotherapy; and
- 3 Following concomitant treatment temozolomide is to be used for a maximum of six cycles of 5 days treatment, at a maximum dose of 200 mg/m².

Notes: Temozolomide is not subsidised for the treatment of relapsed glioblastoma multiforme. Reapplications will not be approved.

Studies of temozolomide show that its benefit is predominantly in those patients with a good performance status (WHO grade 0 or 1 or Karnofsky score >80), and in patients who have had at least a partial resection of the tumour.

Note : Indication marked with a * is an Unapproved Indication.

We also propose to decline the following funding outstanding applications for temozolomide:

- increasing the number of funded treatment cycles beyond the currently specified six cycles;
- treatment following disease relapse; and
- treatment where surgery and/or radiation is contraindicated.

We note that any decision to decline these applications would not prevent PHARMAC from considering further applications for the funding of temozolomide in any, or all, of these settings in the future.

Background

Temozolomide is currently funded for patients with newly diagnosed glioblastoma multiforme (grade 4 astrocytomas). PHARMAC has previously received a funding application to amend the Special Authority criteria applying to temozolomide to include its use in a variety of settings:

- use in anaplastic astrocytomas (grade 3 astrocytomas);
- increasing the number of funded treatment cycles, rather than limited to six cycles;
- treatment following disease relapse; and
- treatment where surgery and/or radiation is contraindicated.

The Cancer Treatments Subcommittee of PTAC (CaTSoP) recommended that the Special Authority criteria be amended to allow funding in newly diagnosed anaplastic astrocytoma, noting that patients with high grade anaplastic astrocytoma were clinically very similar to glioblastoma multiforme patients. CaTSoP recommended declining all other aspects of the application due to an absence of comparative evidence.

We note that temozolomide is not registered by Medsafe for the treatment of patients with newly diagnosed anaplastic astrocytoma, therefore, in this setting it would need to be prescribed and used in accordance with Section 25 of the Medicines Act.