

15 July 2009

Proposal relating to cyclosporin A and clozapine approved

PHARMAC is pleased to announce the approval of the proposal relating to the supply of Neoral (cyclosporin A 25 mg, 50 mg and 100 mg capsules and 100 mg per mL oral liquid) and Clozaril (clozapine 25 mg and 100 mg tablets).

In summary;

In relation to Neoral (cyclosporin A)

- from 1 September 2009 the Special Authority criteria applying to cyclosporin A will be removed meaning that it would be subsidised when prescribed for any indication;
- the Pharmaceutical Schedule listed prices and subsidies for Neoral will remain unchanged, however, from 1 September 2009 a rebate will apply to all community subsidies and hospital dispensings which will reduce the net price; and
- Neoral will have protection from subsidy reduction and delisting until 30 June 2010.

In relation to Clozaril (clozapine)

- The Pharmaceutical Schedule listed prices and subsidies for Clozaril will remain unchanged, however, from 1 June 2009 a rebate will apply to all community subsidies and hospital dispensings which will reduce the net price; and
- Clozaril will have protection from subsidy reduction and delisting until 30 June 2012.

Feedback Received

The proposal was the subject of a consultation letter dated 15 June 2009. We appreciate all the feedback we received and acknowledge the time people took to respond. All consultation responses received by 30 June 2009 were considered in their entirety in making the decision on the proposal.

Consultation responses on the proposal were generally supportive; however, some respondents, in particular dermatologists, considered that the potential side effects of cyclosporin A were significant and it should only be funded only where prescribers are experienced in its use and monitoring.

Whilst acknowledging the potential side effects of cyclosporin A and the need for careful monitoring of patients PHARMAC consider that it is the responsibility of the prescriber to prescribe and monitor appropriately, regardless of whether or not a particular pharmaceutical is funded. In general, such concerns should be addressed through way of regulation by Medsafe rather than by funding restrictions. PHARMAC consider that it is the responsibility of relevant Medical Councils/Professional Bodies

and/or Medsafe to determine which prescribers can and cannot prescribe a particular pharmaceutical.

PHARMAC sought advice on removing the Special Authority from cyclosporin A from the Transplant Immunosuppressant Subcommittee of PTAC in September 2008. The Subcommittee considered that there was no clinical risk in removing the Special Authority but noted that cyclosporin A was a powerful immunosuppressant with a narrow therapeutic index and care was needed to ensure appropriate prescribing. The Subcommittee considered that the risk of misuse from removal of the specialist restriction would be small, noting that prednisone has no such restriction.

More information

If you have any queries about these changes please contact the PHARMAC helpline on 0800 66 00 50 (9 am to 5 pm weekdays).