

26 March 2009

Proposal to widen access to mycophenolate mofetil (CellCept)

PHARMAC is seeking feedback on a proposal to widen access to mycophenolate mofetil (CellCept) for use in liver transplant recipients from 1 July 2009.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by 4 pm on **Thursday, 9 April 2009** to:

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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.

Details of the proposal

The Special Authority criteria for mycophenolate mofetil would be amended from 1 July 2009 as follows to allow for its use following liver transplantation (changes in bold and strikethrough):

Special Authority for Subsidy

Initial application only from a relevant specialist. ~~Approvals valid without further renewal unless notified~~ for applications meeting the following criteria:

Any of the following:

- 1 Renal transplant recipient; or
- 2 Heart transplant recipient; or
- 3 Liver transplant recipient; or**
- ~~3~~ 4 Patient has an organ transplant and has severe tophaceous gout making azathioprine unsuitable.

Approvals valid without further renewal unless notified.

Background

Mycophenolate mofetil (CellCept, Roche Products NZ Ltd) is an immunosuppressant indicated for the prophylaxis of organ rejection in patients receiving allogeneic renal, cardiac or hepatic transplants.

Mycophenolate mofetil is currently funded via Special Authority for renal and heart transplant recipients, or for other organ transplant recipients with severe tophaceous gout making azathioprine unsuitable.

This proposal would mean that funded access for mycophenolate mofetil would be widened to include liver transplant recipients.

Approximately 40 liver transplants are performed in New Zealand every year. Some 10% of liver transplant recipients suffer late-onset renal failure which is difficult to treat and can lead to renal transplantation or death.

The Transplant Immunosuppressant Subcommittee of PTAC considered that the evidence demonstrated that mycophenolate mofetil permits dose reduction of calcineurin phosphatase, with the potential to preserve renal function. The Subcommittee recommended that funded access in the Pharmaceutical Schedule to mycophenolate mofetil be widened to include prophylaxis of renal failure in liver transplant patients and gave this recommendation a medium-to-high priority. The Subcommittee considered that, if funded, transplant clinicians should use mycophenolate mofetil (1 mg BID) in combination with tacrolimus (dose reduced, or dose reduced and dose delayed) and basiliximab.

The widening of access to mycophenolate mofetil for liver transplant recipients is expected to reduce rates of renal dialysis, renal transplantation, re-transplantation and cardiovascular morbidity and mortality associated with progression to end stage renal failure and late rejection in these patients