

3 September 2010

Approval of proposal for funding a new brand of mycophenolate mofetil (Myaccord) and to widen funded access to that brand

PHARMAC is pleased to announce the approval of a proposal that was the subject of a consultation letter dated 17 June 2010.

In summary, the effect of the decision is that from 1 October 2010:

- Douglas Pharmaceutical's brand of mycophenolate mofetil 250 mg capsule and 500 mg tablets (Myaccord) will be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 October 2010.
- Funded access to Myaccord will be subject to Special Authority for transplant recipients and patients with autoimmune diseases that have not responded to other standard immunosuppressant treatments.

This decision is expected to result in approximately 350 additional patients having access to funded mycophenolate each year.

Further details of the decision and feedback can be found below and on the following pages.

Details of the decision

- Myaccord will be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 October 2010 at the following prices and subsidies (ex-manufacturer, excluding GST):

Pharmaceutical	Brand	Form and Strength	Pack Size	Proposed price and subsidy
Mycophenolate mofetil	Myaccord	Cap 250 mg	100	\$85.00
Mycophenolate mofetil	Myaccord	Tab 500 mg	50	\$85.00

- If annual sales of Myaccord reach \$250,000 the price and subsidy will be adjusted as follows (ex-manufacturer, excluding GST):

Brand	Form and Strength	Pack Size	Initial price and subsidy	Adjusted price and subsidy
Myaccord	Cap 250 mg	100	\$85.00	\$70.00
Myaccord	Tab 500 mg	50	\$85.00	\$70.00

- The listing of Myaccord in Section B of the Pharmaceutical Schedule will be subject to the following Special Authority restriction:

Mycophenolate mofetil - Special Authority for Subsidy

Initial application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

1 Transplant recipient; or

2 Both:

Patients with diseases where

2.1 Steroids and azathioprine have been trialled and discontinued because of unacceptable side effects or inadequate clinical response; and

2.2 Either:

Patients with diseases where

2.2.1 Cyclophosphamide has been trialled and discontinued because of unacceptable side effects or inadequate clinical response; or

2.2.2 Cyclophosphamide treatment is contraindicated.

- Myaccord will have protection from subsidy reduction and delisting until 30 June 2012.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 1 July 2010 were considered in their entirety in making a decision on the proposal. Consultation feedback on the proposal was generally supportive; however, some respondents requested changes to the proposed Special Authority and/or access to other patient groups. The following key issues were raised in relation to specific aspects of the proposal:

Theme	Comment
The Special Authority criteria should include bone marrow or stem cell transplant recipients.	<p>We agree that mycophenolate should be funded for prophylaxis of graft versus host disease in bone marrow or stem cell transplant recipients and note that such funding is currently being approved under the Hospital Exceptional Circumstances scheme.</p> <p>We have amended the Special Authority criteria "Organ transplant recipient" to "Transplant recipient" to make it clearer that bone marrow and stem cell transplant recipients are funded.</p>
Criterion 2 should be amended so it is clearer that mycophenolate is funded for "diseases" where steroids etc have not worked.	The Special Authority has been amended to include the line "Patients with diseases where" above the relevant criteria which make the intent of the criteria clearer.

Theme	Comment
<p>Funding was requested for some autoimmune patient groups without need for prior treatment with steroids, azathioprine and/or cyclophosphamide.</p>	<p>The proposed criteria are consistent with the recommendations of the Transplant Immunosuppressant Subcommittee of PTAC. This included specific consideration of patients with Autoimmune Hepatitis and Lupus Nephritis.</p> <p>Although the cost of mycophenolate has decreased significantly it is still much more expensive than steroids, azathioprine and cyclophosphamide, therefore, it is difficult at this time to justify widening access further without evidence of significant clinical benefit, cost-effectiveness and/or a high unmet health need.</p>
<p>Requests that the criteria be amended such that patients would be funded if steroids have been trialled and azathioprine is contraindicated. Considers such patients would include those with severe tophaceous gout.</p>	<p>See above comment. In addition, we note that the current funding for mycophenolate includes organ transplant recipients with severe tophaceous gout in whom azathioprine is unsuitable, these patients would remain eligible for funding under the new criterion 1 "Transplant recipient". We note that mycophenolate is much more expensive than azathioprine, therefore, it is reasonable to require a trial of funded azathioprine prior to mycophenolate</p>
<p>Why is the criteria for cyclophosphamide different to azathioprine and steroids?</p>	<p>The Transplant Subcommittee of PTAC noted that cyclophosphamide may cause infertility therefore its use is specifically contraindicated in some patients, particularly young women of child bearing potential, therefore, a trial of cyclophosphamide is not considered appropriate in all patients.</p>

More information

If you have any questions about this decision, you can call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.