

20 October 2003

To: All pharmaceutical suppliers, medical groups and interested parties.

By facsimile (2 pages including this one)

Consultation on amendment to the listing of Clarithromycin in Section B of the Pharmaceutical Schedule.

PHARMAC has received a submission to widen access to a 500 mg dose of clarithromycin oral liquid, for use as prophylactic treatment of endocarditis prior to dental procedures and preoperatively. This involves no more than a 500 mg stat dose. Currently a 500 mg dose of the tablet formulation is subsidised for this purpose.

The Pharmacology and Therapeutics Advisory Committee (PTAC) considered this submission and recommended that the criteria for clarithromycin tablets and oral liquid should be the same and that access be extended to included paediatricians.

PHARMAC proposes to amend the listing and Special Authority Criteria for clarithromycin oral liquid and tablets as follows:

Clarithromycin

Tab 250 mg.....	9.40	10	✓Klacid
Grans for oral liq 125 mg per 5 ml.....	23.12	70ml	✓Klacid

a) Maximum of 500 mg per prescription; or

b) Special Authority – Retail pharmacy

Subsidy for more than 500 mg per prescription by Special Authority **is available as follows:**

i) General Practitioners and appropriate specialists may apply for:

- eradication of *Helicobacter pylori* in patients with proven infection and endoscopically proven peptic ulcer disease;

- Approvals valid for six months only;

Maximum two prescriptions (two courses) per patient

ii) Respiratory physicians, paediatricians or infectious disease specialists may apply for patients with either:

- Mycobacterium Avium Intracellulare Complex infections in patients with AIDS; or

- Atypical and drug-resistant mycobacterial infections; or

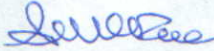
- prophylaxis against disseminated Mycobacterium Avium Intracellulare Complex infections in patients with both HIV infections and CD4 count of 50 or less.

Approvals are valid for two years.

Note: a maximum of 500 mg is intended for use as a single dose in the prophylaxis of endocarditis prior to dental procedures and preoperatively in patients who have an allergy to penicillin or are currently on antibiotic treatment with another agent.

Responses to this proposal will be considered by the PHARMAC Chief Executive or PHARMAC Board in November 2003. If you wish to make comments on this proposal, please forward them to PHARMAC attention Adam McRae, Therapeutic Group Manager Intern by **5pm Friday, 7 November 2003**.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Adam McRae', written in a cursive style.

Adam McRae
Therapeutic Group Manager Intern