

22 April 2008

## **Proposal to amend restrictions on alimentary tract and metabolism pharmaceuticals**

PHARMAC is seeking public feedback on a proposal to alter restrictions on 13 medicines. This letter outlines the proposal and how you can provide your feedback on it.

### ***Proposal Summary***

PHARMAC is proposing to amend the restrictions that currently apply to a group of Alimentary Tract and Metabolism pharmaceuticals in Section B of the Pharmaceutical Schedule, as detailed on the following pages, with effect from 1 July 2008.

The medicines in the proposal include antidiarrhoeals, antispasmodics and other agents altering gut motility, antiulcerants, diabetes, digestives including enzymes, mouth and throat, and vitamins. In most cases the changes involve removal of the "Specialist" restriction, meaning that prescriptions written by other types of practitioners would no longer require a specialist endorsement for subsidy.

### ***Feedback sought***

We welcome your feedback on this proposal. To provide feedback on this proposal please submit it in writing by **5 pm, Friday 9 May 2008** to:

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### ***What will happen then?***

All of the submissions we receive before the deadline will be considered by PHARMAC's Board (or Chief Executive, acting under delegated authority) when making a decision on whether to implement this proposal.

If the proposal is approved, it is anticipated that the proposed changes would take effect from 1 July 2008.

### ***Details of the proposal***

Proposed amendments to the Pharmaceutical Schedule are as follows (deletions shown in strikethrough, additions in **bold**):

### *Antidiarrhoeals*

- BUDESONIDE – Special Authority see SA0698 below – Retail pharmacy  
Cap 3 mg

SA0698 Special Authority for Subsidy

Initial application ~~only~~ from **any relevant practitioner a gastroenterologist, general surgeon or general physician**. Approvals valid for 3 months for applications meeting the following criteria:

Both:

1. Mild to moderate ileal, ileocaecal or proximal Crohn's disease; and
2. Any of the following:
  - 2.1 Diabetes; or
  - 2.2 Cushingoid habitus; or
  - 2.3 Osteoporosis where there is significant risk of fracture; or
  - 2.4 Severe acne following treatment with conventional corticosteroid therapy.

Renewal ~~only~~ from **any relevant practitioner a gastroenterologist, general surgeon or general physician**. Approvals valid for 3 months where the treatment remains appropriate and the patient is benefiting from treatment.

- OLSALAZINE – ~~Retail pharmacy Specialist~~  
Tab 500 mg  
Cap 250 mg
- SODIUM CROMOGLYATE – ~~Retail pharmacy Specialist~~  
Cap 100 mg

### *Antispasmodics and Other Agents Altering Gut Motility*

- MEBEVERINE HYDROCHLORIDE – ~~Retail pharmacy Specialist~~  
Tab 135 mg

### *Antiulcerants*

- MISOPROSTOL – ~~Retail pharmacy Specialist~~  
Tab 200 µg
- RANITIDINE HYDROCHLORIDE – Only on a prescription  
Oral liq 150 mg per 10 ml – ~~Subsidy by endorsement~~

~~Oral liquid is subsidized for patients:~~

- ~~1. with oesophageal stricture, or~~
- ~~2. in terminal care, or~~
- ~~3. who are either too young or too old to swallow conventional tablets and the prescription is endorsed accordingly~~

~~Note: the cost of treatment with ranitidine oral liquid is more than 10 times higher than that of ranitidine tablets. Following the derestriction of access PHARMAC will be monitoring expenditure on ranitidine oral liquid more closely and may, subject to consultation and PHARMAC Board approval, restrict access again if expenditure was to grow substantially.~~

## Diabetes

- ACARBOSE – Special Authority see SA0490 below – Retail pharmacy  
Tab 50 mg  
Tab 100 mg

SA0490 Special Authority for Subsidy

Initial application ~~only~~ from **any relevant practitioner** ~~a relevant specialist~~. Approvals valid ~~for 2 years~~ **without renewal** ~~for 2 years~~ for applications **where the patient has type 2 diabetes and where metformin is either not tolerated following an adequate trial or where metformin is contraindicated** meeting the following criteria:

~~Any of the following:~~

- ~~1. Requires but is not able to tolerate metformin therapy; or~~
- ~~2. Requires metformin but metformin is contraindicated; or~~
- ~~3. Has not responded to or tolerated the maximum appropriate dose of metformin.~~

~~Renewal only from a relevant specialist. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.~~

## Digestives Including Enzymes

- PANCREATIC ENZYME – ~~Retail pharmacy~~ Specialist  
Cap EC 8,000BP u lipase, 9,000BP u amylase, 210BP u protease  
Cap EC 10,000 BP u lipase, 9,000 BP u amylase and 210 BP u protease  
Cap EC 25,000 BP u lipase, 18,000 BP u amylase, 1,000 BP u protease  
Cap EC 25,000 BP u lipase, 22,500 BP u amylase, 1,250 BP u protease
- URSODEOXYCHOLIC ACID – Special Authority see SA0841 below – Retail pharmacy  
Cap 300 mg

SA0841 Special Authority for Subsidy

Initial application ~~only~~ from **any relevant practitioner** ~~a gastroenterologist or general physician~~.

Approvals valid for 6 months for applications meeting the following criteria:

Both:

1. Primary biliary cirrhosis confirmed by antimitochondrial antibody titre (AMA) > 1:80, and raised cholestatic liver enzymes with or without raised serum IgM or, if AMA is negative, by liver biopsy; and
2. Patient not requiring a liver transplant (bilirubin > 170umol/l; decompensated cirrhosis).

Note: Liver biopsy is not usually required for diagnosis but is helpful to stage the disease.

Renewal ~~only~~ from **any relevant practitioner** ~~a gastroenterologist or general physician~~. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

Note: Actigall is not an appropriate therapy for patients requiring a liver transplant (bilirubin > 170 micromol/l; decompensated cirrhosis). These patients should be referred to an appropriate transplant centre. Treatment failure – doubling of serum bilirubin levels, absence of a significant decrease in ALP or ALT and AST, development of varices, ascites or encephalopathy, marked worsening of pruritus or fatigue, histological progression by two stages, or to cirrhosis, need for transplantation.

## Mouth and Throat

- BENZYLAMINE HYDROCHLORIDE – ~~Retail pharmacy~~ Specialist  
Soln 0.15%

## Vitamins

- ALFACALCIDOL – ~~Retail pharmacy Specialist~~
  - Cap 0.25 µg
  - Cap 1 µg
  - Oral drops 2 µg per ml
- CALCITRIOL – ~~Retail pharmacy Specialist~~
  - Cap 0.25 µg
  - Cap 0.5 µg
  - Oral liq 1 µg per ml
- ALPHA TOCOPHERYL ACETATE – Special Authority see SA0264 below – Hospital pharmacy [HP3]
  - Water solubilised soln 156 iu/ml, with calibrated dropper

SA0264 Special Authority for Subsidy

Initial application ~~only~~ from **any relevant practitioner** a ~~paediatrician or respiratory specialist~~.

Approvals valid for 2 years for applications meeting the following criteria:

Either:

1. Cystic fibrosis patient; or

Both:

2. Infant or child with liver disease or short gut syndrome; and
3. Requires vitamin supplementation.

Renewal only from any relevant practitioner a paediatrician or respiratory specialist. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.