

2 September 2005

To all interested parties

**Notification of changes to the Pharmaceutical Schedule*****Widening of access to subsidies for alendronate 10mg and 70mg tablets***

PHARMAC is pleased to advise that the PHARMAC Board has resolved to widen access to subsidies for alendronate 10mg and 70mg tablets. Thank you to all those who responded to the 5 August 2005 consultation letter on the above proposal. The proposal means that:

- the following strengths of Fosamax (alendronate) will be listed in Part II of Section H of the Pharmaceutical Schedule from 1 October 2005 at the prices indicated below:

Chemical	Strength	Pack size	Proposed price
Alendronate	10 mg	30 tablets	\$42.75
Alendronate	70 mg	4 tablets	\$39.90

- the prices and subsidies of Fosamax (alendronate) in Section B of the Pharmaceutical Schedule will be reduced from 1 October 2005 as per the following table:

Chemical	Strength	Pack size	Current price and subsidy	Proposed price and subsidy
Alendronate	10 mg	30 tablets	\$45.00	\$42.75
Alendronate	70 mg	4 tablets	\$42.00	\$39.90

- the Special Authority restriction applying to Fosamax (alendronate) will be replaced from 1 October 2005 with the following:

**SPECIAL AUTHORITY CRITERIA FOR ALENDRONATE****Special Authority for Manufacturers Price**

Initial application - (Underlying cause - Osteoporosis) – only from a relevant Specialist or vocationally registered General Practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

- History of one significant osteoporotic fracture demonstrated radiologically and documented bone mass density (BMD)  $\geq 2.5$  standard deviations below the mean normal value in young adults (i.e. T-Score  $\leq -2.5$ ); or

- 2 History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons. It is unlikely that this provision would apply to many patients under 75 years of age; or
- 3 History of two significant osteoporotic fractures demonstrated radiologically; or
- 4 Documented T-Score  $\leq -3.0$ .

Initial application - (Underlying cause – glucocorticosteroid therapy) – only from a relevant Specialist or vocationally registered General Practitioner. Approvals valid for 1 year for applications meeting the following criteria:

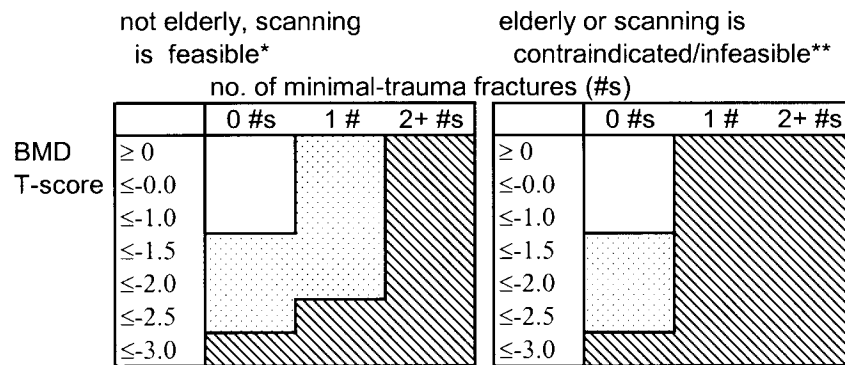
Both:



- 5.1 The patient is receiving systemic glucocorticosteroid therapy ( $\geq 5$  mg per day prednisone equivalents) and has already received or is expected to receive therapy for more than three months; and
- 5.2 Either:
  - 5.2.1 has documented BMD  $\geq 1.5$  standard deviations below the mean normal value in young adults (i.e. T-Score  $\leq -1.5$ ); or
  - 5.2.2 has a history of one significant osteoporotic fracture demonstrated radiologically.

Renewal only from a relevant Specialist or vocationally registered General Practitioner. Approvals valid for 1 year where the patient is continuing systemic glucocorticosteroid therapy ( $\geq 5$  mg per day prednisone equivalents).

Notes:

1. The above criteria can be summarised diagrammatically as follows:



 all patients  
 glucocorticosteroid users at risk of severe osteoporosis  
 \*includes most patients <75 years      \*\*includes patients aged 75+ years

2. Evidence used by National institute for Clinical Excellence (NICE) guidance indicates that patients aged 75 years and over who have a history of significant osteoporotic fracture demonstrated radiologically are very likely to have a T-Score  $\leq -2.5$ , and therefore do not require BMD measurement for treatment with bisphosphonates.
3. Osteoporotic fractures are the incident events for severe (established) osteoporosis, and can be defined using the WHO definitions of fragility fracture and osteoporosis. The WHO defines severe (established) osteoporosis as a T-score below  $-2.5$  with one or more associated fragility

fractures. Fragility fractures are fractures that occur as a result of mechanical forces that would not ordinarily cause fracture (minimal trauma). The WHO has quantified this as forces equivalent to a fall from a standing height or less.

4. In line with the Australian guidelines for funding alendronate, a vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

- Fosamax (alendronate) 10 mg tablets will be delisted from both Sections B and H from 1 April 2006;
- the prices and (where applicable) subsidies of Fosamax (alendronate) will be reduced in Sections B and H of the Pharmaceutical Schedule from 1 October 2006 as per the following table:

Chemical	Strength	Pack size	Subsidy at 30 September 2006	Proposed price
Alendronate	70 mg	4 tablets	\$39.90	\$35.91

- PHARMAC will not otherwise reduce the subsidy for Fosamax before 1 January 2009.
- Fosamax will also be subject to a confidential risk-sharing arrangement.

### ***Implementation issues and feedback on consultation***

PHARMAC received many submissions in response to our consultation on this proposal. Many of the points raised by respondents and the Pharmacology and Therapeutics Advisory Committee (PTAC) have resulted in slight changes to the proposal. The key issues raised and an outline of how they have been taken into consideration, is provided below:

1. A number of respondents sought clarification of the term “significant osteoporotic fracture” as set out in criteria 1, 2 and 3. PHARMAC staff note that the term “significant osteoporotic fracture” was used in the current criteria and has not, to our knowledge caused any problems. However, the new criteria include a note defining osteoporotic fracture, in particular the paucity of trauma leading to fragility fractures.
2. A common concern was about the possible ambiguity associated with criterion #2. The wording of this criterion has been amended to address these concerns. In particular, PHARMAC has now included an age guide and clearer definition of what it considers to be valid reasons for not needing to conduct a BMD scan.
3. Concerns were expressed by some respondents regarding the lack of long-term safety data for alendronate. There was also concern that common fractures in elderly women such as hip and wrist fractures may incorrectly be diagnosed as osteoporotic fractures thus leading to inappropriate medication being given to some women.

PHARMAC staff consider that these concerns were fully considered by PHARMAC’s expert advisors, including PTAC, in the development of the proposal. We consider that the benefits of treatment with alendronate are likely to outweigh the possible risks. We also note that best evidence seems to suggest that treatment with alendronate results in major (50%) reductions in hip, wrist and vertebral fracture rates, which is important for those groups of patients at high risk of further fracture. It is these patients that the new criteria intend to cover. We acknowledge

that the evidence for long-term effects on bone at this stage is low grade, and requires heightened awareness, but note that this is the case with many medicines.

While PHARMAC sets access criteria and should do so responsibly, clinicians and patients are the final decision-makers when it comes to determining whether treatment is appropriate in individual cases.

4. Some respondents considered that bone mineral density (BMD) is not an accurate predictor of osteoporotic risk and considered that a number of factors need to be accounted for such as low body weight, current smoking, corticosteroid use, untreated premature menopause, maternal hip fracture before the age of 75, and other medical conditions (such as thyroid conditions, Coeliac and Crohn's disease etc.) associated with bone loss and prolonged immobility.

PHARMAC staff note that age and BMD are known to be the strongest predictors of risk of fragility fracture, even if insufficient in themselves alone. BMD is a key criterion in guidelines internationally. The impact of other risk factors for determining overall which patients would benefit most from treatment has not yet been quantified in a practical way. We consider that inclusion of other risk factors should be at the discretion of the prescribing clinician rather than a requirement and an added complexity to the Special Authority criteria.

5. It was noted that there are a few patients who cannot tolerate the 70 mg dose and are taking the 10 mg dose every day and that these patients will be disadvantaged when the 10 mg tablet ceases to be available.

PHARMAC staff acknowledge this point and note that the discontinuation of the 10mg dose is a global initiative beyond PHARMAC's control or influence.

We trust that this letter helps to answer your queries. Please contact me if you have further concerns.

Yours sincerely



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