

30 July 2009

Proposal relating to alendronate, aprepitant, raltegravir, levodopa with carbidopa, timolol and dorzolamide with timolol

Proposal summary

PHARMAC is seeking feedback on a proposal to fund the anti-nausea treatment aprepitant (Emend), the antiretroviral agent raltegravir (Isentress) and a new strength of alendronate with cholecalciferol (Fosamax Plus), through a provisional agreement with Merck Sharp & Dohme (New Zealand) Limited (MSD).

This proposal would also change the terms of listing of alendronate sodium (Fosamax), the existing funded strength of alendronate sodium with cholecalciferol (Fosamax Plus), levodopa with carbidopa (Sinemet & Sinemet CR), timolol maleate (Timoptol XE) and dorzolamide hydrochloride with timolol (Cosopt), through the same provisional agreement.

Key aspects of the proposal are as follows (all would be implemented 1 October 2009 unless otherwise stated):

Alendronate sodium, with and without cholecalciferol (Fosamax and Fosamax Plus)

- A new strength of Fosamax Plus tablets (alendronate sodium 70 mg with cholecalciferol 5600 iu) would be funded, subject to Special Authority criteria, and the existing funded strength of Fosamax Plus would be delisted following discontinuation of supply by MSD.
- The Special Authority criteria for "Alendronate for Osteoporosis" would be amended.

Aprepitant (Emend)

- Emend capsules would be funded, subject to Special Authority criteria.

Raltegravir (Isentress)

- Isentress would be funded subject to Special Authority criteria.

Levodopa with carbidopa (Sinemet and Sinemet CR)

- The price and subsidy for Sinemet and Sinemet CR would be reduced.
- The "Specialist" restriction would be removed from Sinemet CR.

Timolol maleate and dorzolamide hydrochloride with timolol maleate (Timoptol XE and Cosopt)

- The price and subsidy for Cosopt would be reduced; there would be no changes to the listing of Timoptol XE.

Further details, including how to provide feedback on this proposal, can be found on the following pages.

Feedback sought

We welcome your feedback on this proposal. To provide feedback please submit an email, fax or letter by **4 pm, Thursday 13 August 2009** to:

Geraldine MacGibbon Email: geraldine.macgibbon@pharmac.govt.nz
Therapeutic Group Manager Fax: (04) 460 4995
PHARMAC
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All feedback received before the closing date will be considered when a decision is made on this proposal by PHARMAC's Board (or Chief Executive under delegated authority).

Further details of the Proposal

Alendronate sodium with and without cholecalciferol (Fosamax and Fosamax Plus)

Fosamax and Fosamax Plus would be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 October 2009 at the following prices and subsidies (ex-manufacturer, excluding GST):

Product	Brand	Form and Strength	Pack Size	Proposed price and subsidy from 1 Oct 2009	Proposed price and subsidy from 1 May 2011	Proposed price and subsidy from 1 July 2014
Alendronate sodium	Fosamax	Tab 70 mg	4	\$35.91*	\$22.90	\$12.90
Alendronate sodium with cholecalciferol	Fosamax Plus	Alendronate tab 70 mg with cholecalciferol 2800 iu	4	\$35.91*	Delisted	Delisted
Alendronate sodium with cholecalciferol	Fosamax Plus	Alendronate tab 70 mg with cholecalciferol 5600 iu	4	\$35.91	\$22.90	\$12.90

* no change in price or subsidy from the current listed price and subsidy.

MSD would discontinue supply of the existing funded strength of Fosamax Plus (alendronate sodium 70 mg with cholecalciferol 2800 iu) from approximately October 2009 and PHARMAC would delist it from the Pharmaceutical Schedule approximately 6 months later.

A confidential rebate would apply to community subsidies and hospital dispensings of Fosamax and both strengths of Fosamax Plus, which would reduce the net subsidy and price.

Fosamax and the higher strength of Fosamax Plus (alendronate sodium 70 mg with cholecalciferol 5600 iu) would have protection from delisting and subsidy reduction until 1 August 2018.

Fosamax and Fosamax Plus would be subject to the current Special Authority restrictions, except that, as recommended by the Osteoporosis Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC), a new criterion would be added to the “Alendronate for Osteoporosis” Special Authority initial application for “Underlying cause – Osteoporosis” and renewal application for “Underlying cause was glucocorticosteroid therapy but patient now meets the ‘Underlying cause – osteoporosis’ criteria” as follows (additions in bold):

Any of the following:

- 1 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; or
- 5 **A 10-year risk of hip fracture \geq 3%.**

The listing of alendronate sodium 40 mg (Fosamax) in Section B of the Pharmaceutical Schedule would remain unchanged. Alendronate sodium 40 mg (Fosamax) would also be listed in Section H of the Pharmaceutical Schedule from 1 October 2009 at a price of \$133.00 per 30 tablets.

Aprepitant (Emend)

Emend would be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 October 2009 at a price and subsidy of \$116.00 per tri-pack (two 80 mg capsules and one 125 mg capsule) (ex-manufacturer, excluding GST).

Aprepitant in Section B of the Pharmaceutical Schedule would be subject to the following Special Authority restrictions:

Initial application from any relevant practitioner. Approvals valid for 12 months where the patient is undergoing highly emetogenic chemotherapy and/or anthracycline-based chemotherapy for the treatment of malignancy.

Renewal from any relevant practitioner. Approvals valid for 12 months where the patient is undergoing highly emetogenic chemotherapy and/or anthracycline-based chemotherapy for the treatment of malignancy.

Emend would have protection from delisting and subsidy reduction until 1 July 2014.

Raltegravir (Isentress)

Isentress tablets would be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 October 2009 as follows (ex-manufacturer, excluding GST):

Product	Brand	Form and Strength	Pack Size	Proposed price and subsidy from 1 October 2009	Proposed price and subsidy from 1 January 2011
Raltegravir potassium	Isentress	Tab 400 mg	60	\$1,350.00	\$1,090.00

A rebate would apply to community subsidies and hospital dispensings of Isentress, which would reduce the net subsidy and price of Isentress.

Raltegravir potassium listed in Section B of the Pharmaceutical Schedule would be subject to the same Special Authority restrictions that apply to the funded Antiretrovirals (Non-nucleosides Reverse Transcriptase Inhibitors, Nucleosides Reverse Transcriptase Inhibitors and Protease Inhibitors) at 1 October 2009.

Isentress would have protection from delisting and subsidy reduction until 1 July 2014.

Levodopa with carbidopa (Sinemet and Sinemet CR)

From 1 October 2009 Sinemet and Sinemet CR would be listed in Part II of Section H of the Pharmaceutical Schedule, and the prices and subsidies of two strengths of Sinemet and Sinemet CR would change in Section B of the Pharmaceutical Schedule, as follows (ex-manufacturer, excluding GST):

Product	Brand	Form and Strength	Pack Size	Current price and subsidy	Proposed price and subsidy
Levodopa with carbidopa	Sinemet	Levodopa tablet 100 mg with carbidopa 25 mg	100	\$20.00	\$20.00
Levodopa with carbidopa	Sinemet	Levodopa tablet 250 mg with carbidopa 25 mg	100	\$57.50	\$40.00
Levodopa with carbidopa	Sinemet CR	Levodopa long-acting tablet 200 mg with carbidopa 50 mg	100	\$70.00	\$47.50

The “Retail pharmacy-Specialist” restriction would be removed from the listing of levodopa long-acting tablet 200 mg with carbidopa 50 mg (Sinemet CR) in Section B of the Pharmaceutical Schedule from 1 October 2009.

Sinemet and Sinemet CR would have protection from delisting and subsidy reduction until 1 July 2012.

Dorzolamide hydrochloride with timolol maleate (Cosopt)

The price and subsidy for dorzolamide hydrochloride eye drops 2% with timolol maleate 0.5% (Cosopt) would reduce from \$18.50 to \$15.50 per 5 ml OP in Section B of the Pharmaceutical Schedule from 1 October 2009 (ex-manufacturer, excluding GST).

Dorzolamide hydrochloride eye drops 2% with timolol maleate 0.5% (Cosopt) would be listed in Part II of Section H of the Pharmaceutical Schedule at a price of \$15.50 per 5 ml from 1 October 2009 (ex-manufacturer, excluding GST).

A confidential rebate would apply to community subsidies and hospital dispensings of Cosopt from 1 January 2012, which would reduce the net subsidy and price of Cosopt.

Cosopt would have protection from delisting and subsidy reduction until 1 January 2014.

Timolol maleate (Timoptol XE)

Timolol maleate eye drops (Timoptol XE) would be listed in Part II of Section H of the Pharmaceutical Schedule from 1 October 2009 at the following prices (ex-manufacturer, excluding GST):

Product	Brand	Form and Strength	Pack Size	Proposed Price
Timolol maleate	Timoptol XE	Eye drops 0.25%, gel forming	2.5 ml	\$3.30
Timolol maleate	Timoptol XE	Eye drops 0.5%, gel forming	2.5 ml	\$3.78

Both strengths of Timoptol XE would continue to be listed in Section B of the Pharmaceutical Schedule from 1 October 2009 at the above prices and subsidies (ex-manufacturer, excluding GST).

Timoptol XE would have protection from delisting and subsidy reduction until 1 January 2014.

Background to the Proposal

In June 2009 PHARMAC initiated patent revocation proceedings in the High Court challenging the validity of Merck & Co, Inc (Merck)'s patent NZ501807 relating to the use of alendronate for the manufacture of a medicament for inhibiting bone resorption where the medicament is in a unit dosage form which comprises about 70mg and has a dosing interval of once weekly. Merck opposes those proceedings.

If the current proposal is approved, this court action, and associated court action commenced by Merck, will be withdrawn.

Merck's patent NZ501807 expires on 17 July 2018.