CONSULTATION

PHARMAC
Pharmaceutical Management Agency

11 March 2013

Proposal relating to amiloride, perindopril and trandolapril

PHARMAC is seeking feedback on a proposal to fund new brands of the potassium-sparing diuretic amiloride hydrochloride (Apo-Amiloride) and the ACE inhibitor perindopril (Apo-Perindopril) through an agreement with Apotex NZ Limited; to alter the subsidy arrangement for the existing funded brand of perindopril (Coversyl); and to clarify the subsidy arrangement for trandolapril (Gopten). In summary:

- Apo-Amiloride (amiloride hydrochloride 5 mg tablets) would be fully funded from 1 July 2013;
- Apo-Perindopril (perindopril 2 mg and 4 mg tablets) would be fully funded from 1 May 2013;
- the subsidies for Coversyl (perindopril 2 mg and 4 mg tablets) would be adjusted to match the Apo-Perindopril subsidies from 1 May 2013;
- the higher subsidy for Coversyl by endorsement for patients with congestive heart failure who were taking perindopril prior to 1 June 1998 would be removed from 1 May 2013. This would mean that any patient currently receiving the higher subsidy by endorsement would need to switch to the Apo-Perindopril brand to remain on a fully subsidised product; and
- the wording of the higher subsidy by endorsement for Gopten (trandolapril 1 mg and 2 mg capsules), which is also available for patients with congestive heart failure who were taking it prior to 1 June 1998, would be amended for clarity.

Details of the proposal are provided on the following pages.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Monday, 25 March 2013** to:

Geraldine MacGibbon
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PHARMAC

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All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal. Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like withheld.

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Details of the proposal

- Apo-Amiloride and Apo-Perindopril would be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule as follows (prices and subsidies expressed ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	List date	Proposed price and subsidy
Amiloride hydrochloride	Tab 5 mg	Apo-Amiloride	100	1 July 2013	$17.50
Perindopril	Tab 2 mg	Apo-Perindopril	30	1 May 2013	$3.75
Perindopril	Tab 4 mg	Apo-Perindopril	30	1 May 2013	$4.80

- The subsidies for the Coversyl brand of perindopril tablets would be increased from 1 May 2013 as follows:

Chemical	Presentation	Brand	Pack size	Current subsidy (and price)	Proposed subsidy (and price)
Perindopril	Tab 2 mg	Coversyl	30	$3.00 ($18.50)	$3.75 ($18.50)
Perindopril	Tab 4 mg	Coversyl	30	$4.05 ($25.00)	$4.80 ($25.00)

- The higher subsidy by endorsement that currently applies to the Coversyl brand of perindopril tablets would be removed from 1 May 2013.

- The higher subsidy by endorsement that currently applies to the Gopten brand of trandolapril capsules would be amended from 1 May 2013 as follows (deletions in strikethrough, additions in bold):

  Higher subsidy by endorsement is available ~~Trandolapril will be funded to the level of the ex-manufacturer price listed in the Schedule~~ for patients who were taking ~~these ACE inhibitors~~ **trandolapril** for the treatment of congestive heart failure prior to 1 June 1998. The prescription must be endorsed accordingly. We recommend that the words used to indicate eligibility are "certified condition" or an appropriate description of the patient such as "congestive heart failure", "CHF", "congestive cardiac failure" or "CCF". ~~Definition of Congestive Heart Failure At the request of some prescribers the PTAC Cardiovascular subcommittee has provided a definition of congestive heart failure for the purposes of the funding of the manufacturer's surcharge: "Clinicians should use their clinical judgement. Existing patients would be eligible for the funding of the surcharge if the patient shows signs and symptoms of congestive heart failure, and requires or has in the past required concomitant treatment with a diuretic. The definition could also be considered to include patients post myocardial infarction with an ejection fraction of less than 40%."~~ **For the purposes of this endorsement, congestive heart failure includes patients post myocardial infarction with an ejection fraction of less than 40%. Patients who started on trandolapril after 1 June 1998 are not eligible for full subsidy by endorsement.**

Background

Amiloride

Amiloride 5 mg tablets (Midamor) were listed fully funded in the Pharmaceutical Schedule until 1 January 2005, when they were delisted due to discontinuation by the supplier. The Cardiovascular Subcommittee of the Pharmacology and Therapeutics Advisory Committee has expressed its desire for amiloride to be re-listed in the Schedule.

Perindopril and trandolapril

The subsidies for perindopril and trandolapril were reduced in mid 1998 as a result of application of reference pricing across the angiotensin-converting-enzyme (ACE) inhibitor therapeutic subgroup. The suppliers of these products did not lower their prices to match the new subsidies, resulting in a manufacturer's surcharge. At the time, provision was made to allow patients who were already taking these treatments for congestive heart failure (CHF) to continue to access them fully funded via prescription endorsement.

This proposal would result in a fully subsidised brand of perindopril being available for all patients, without the requirement of a prescription endorsement. The endorsement that currently applies to the Coversyl brand would be removed, and patients currently accessing the Coversyl brand of perindopril fully subsidised would need to switch to Apo-Perindopril in order to remain on a fully subsidised brand.

We are aware that the wording of the endorsement may not have clearly expressed its intent, which was that it was only intended to apply to patients taking perindopril or trandolapril for CHF prior to 1 June 1998. The intent of the proposed changes to the wording of the endorsement for trandolapril is to make this clearer (i.e. that the higher subsidy is not available to new patients).