

30 November 2011

Candesartan – Access Widening and Sole Supply

The PHARMAC Board has approved a proposal to widen the candesartan Special Authority access criteria and to have candesartan supplied under a Sole Supply arrangement.

In summary, the decisions will mean:

- **Access** - The candesartan Special Authority access criteria will be widened and the daily dose dispensing restrictions will be removed from 1 August 2012.
- **Sole Supply** – Mylan's Candestar brand of candesartan will be the sole supply brand – its price/subsidy will be reduced and the Atacand brand will be reference priced (1 August 2012) and then the Atacand brand will be delisted (1 November 2012).

Candestar will be the only funded brand of candesartan in the Community and the only brand available in DHB hospitals from 1 November 2012 until 30 June 2015. The decision is expected to result in savings in excess of \$13 million per annum. These savings would be used for the funding of other medicines.

These proposals arose from a Request for Proposals process and were the subject of a consultation letter dated 27 October 2011. This can be found on PHARMAC's website at <http://www.pharmac.govt.nz/2011/10/27?q=candesartan>.

Details of the decisions

Mylan's brand of candesartan tablets (Candestar) has been awarded Sole Supply Status and Hospital Supply Status. This means that it will be the only brand of candesartan tablets subsidised in the Pharmaceutical Schedule, and the only brand available in DHB hospitals (subject to a 1% Discretionary Variance Limit). Sole Supply Status and Hospital Supply Status will be effective from 1 November 2012 and will expire on 30 June 2015.

In addition, the candesartan Special Authority will be widened and the current daily dose dispensing restrictions will be removed. The new Special Authority will be as follows:

INITIAL APPLICATION - ACE inhibitor intolerance

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

Prerequisites (tick boxes where appropriate)

Patient has persistent ACE inhibitor induced cough that is not resolved by ACE inhibitor retriial (same or new ACE inhibitor)

or

Patient has a history of angioedema

INITIAL APPLICATION - Unsatisfactory response to ACE inhibitor

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

Prerequisites (tick box where appropriate)

Patient is not adequately controlled on maximum tolerated dose of an ACE inhibitor

The timelines for these changes to occur are as follows:

- 1 August 2012 – Price reduction for Candestar, reference pricing of Atacand, and the new access criteria (new Special Authority criteria and removal of the current daily dose dispensing restrictions) will come into effect.
- 1 November 2012 – Atacand will be delisted.

The timing of the candesartan price and subsidy (ex-manufacturer, excluding GST) changes are shown below:

Strength	Brand	Pack Size	Subsidy and Price* (Price in brackets if different to subsidy)		
			Current	1 August 2012 to 31 October 2012	1 November 2012
4 mg tablet	Candestar	90	\$48.66	\$4.13	\$4.13
	Atacand	30	\$16.22	\$1.38 (\$16.22)**	Delisted
8 mg tablet	Candestar	90	\$57.90	\$6.10	\$6.10
	Atacand	30	\$19.30	\$2.03 (\$19.30)**	Delisted
16 mg tablet	Candestar	90	\$70.62	\$10.18	\$10.18
	Atacand	30	\$23.54	\$3.39 (\$23.54)**	Delisted
32 mg tablet	Candestar	90	\$115.50	\$17.66	\$17.66
	Atacand	30	\$38.50	\$5.89 (\$38.50)**	Delisted

*Subsidies and prices ex-manufacturer, excluding GST

**This is the current price. It is at the supplier's discretion as to whether this would be reduced to the subsidy level so that the product remains fully funded.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 11 November 2011 were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposal given the therapeutic equivalence and the size of the savings however the following issues were raised in relation to specific aspects of the proposal:

Theme	Comment
Consideration should be given to how intolerance, if it does occur, when patients switch candesartan brands [from Atacand to Candestar], will be addressed.	Because Candestar is bioequivalent to Atacand, we do not expect patients to have difficulties. In the event that some patients are dissatisfied with Candestar, losartan will be available without restriction (the Special Authority that applies to losartan is being removed from 1 December 2011).

Theme	Comment
Why not remove the candesartan Special Authority?	The price of candesartan has historically been much higher than that of the ACE inhibitors. This led to candesartan being targeted to patients for whom ACE inhibitors are not appropriate. Candesartan is still more expensive than the ACE inhibitors and we need to further evaluate the costs and benefits of removing the Special Authority. We will continue to consider this against other investment options and in the mean time will widen access and remove the tablet restriction from 1 August 2012.
Larger candesartan doses (>32 mgs) have an additional anti-proteinuric effect (independent of any anti-hypertensive effect) in many patients with significant proteinuric renal diseases and such an effect may translate into reduced CKD renal disease progression.	As the tablet restrictions will be removed from 1 August 2012, the proposal will provide a subsidy for higher candesartan doses should the prescribing clinician consider this beneficial.
Do the proposed access criteria cover heart failure patients?	The criteria are not indication specific, they include all patients who have ACE inhibitor induced cough, a history of angioedema, or who do not obtain a satisfactory response from ACE inhibitors.

More information

If you have any questions about this decision, you can call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.