

10 June 2013

Approval of proposal to fund ticagrelor for acute coronary syndromes

PHARMAC is pleased to announce the approval of an agreement with AstraZeneca to fund ticagrelor (Brilinta) from 1 July 2013.

This proposal was the subject of a consultation letter dated 26 March 2013 which can be found on PHARMAC's website at <http://www.pharmac.health.nz/news/item/proposal-to-list-ticagrelor>.

Details of the decision

- Ticagrelor (Brilinta) will be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 July 2013 at the following prices and subsidies (expressed ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack Size	Price and subsidy
Ticagrelor	Tablet 90 mg	Brilinta	56	\$90.00

- Ticagrelor will be funded subject to the following Special Authority restrictions in Section B of the Pharmaceutical Schedule:

Special Authority for Subsidy

Initial application (acute coronary syndrome) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- Patient has recently been diagnosed with an ST-elevation or a non-ST-elevation acute coronary syndrome; and
- Fibrinolytic therapy has not been given in the last 24 hours and is not planned.

Renewal (subsequent acute coronary syndrome) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- Patient has recently been diagnosed with another ST-elevation or non-ST-elevation acute coronary syndrome; and
- Fibrinolytic therapy has not been given in the last 24 hours and is not planned.

- Ticagrelor will be subject to the following prescribing restriction in Part II of Section H of the Pharmaceutical Schedule:

RESTRICTED

Restricted to treatment of acute coronary syndromes specifically for patients who have recently been diagnosed with an ST-elevation or a non-ST-elevation acute coronary syndrome, and in whom fibrinolytic therapy has not been given in the last 24 hours and is not planned.

- Ticagrelor will be available under stat dispensing (three months all-at-once) in the community; and
- Confidential pricing arrangements will apply to ticagrelor in the form of annual expenditure caps, above which rebates will apply.

Changes from consultation

The Special Authority criteria and hospital restrictions are simpler and wider than those publicly consulted on. Patients with non-ST elevation myocardial infarction (NSTEMI) no longer need to meet more restrictive criteria than ST elevation myocardial infarction (STEMI) patients. Ticagrelor may be prescribed following a “recent” event, rather than restricting it to within 24 hours of diagnosis. There is also no requirement to avoid clopidogrel loading doses or be clopidogrel-allergic.

These changes were made to simplify the prescribing of ticagrelor, particularly for prescribers applying for the Special Authority approval outside of the hospital setting. The revised Special Authority criteria were accepted by the supplier, subject to some amendments to the annual expenditure cap and rebate confidential pricing arrangement.

Feedback received

We appreciate all the feedback we received and acknowledge the time people took to respond. All consultation responses received were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposal and the following common issues were raised:

Theme	Comment
Prasugrel was considered to have a similar efficacy to ticagrelor and should have similar restrictions placed on it.	<p>PTAC has considered the evidence for prasugrel and recommended that it be funded only for the following patient groups:</p> <ul style="list-style-type: none">• Patients who experience stent thrombosis whilst on clopidogrel;• Patients who have undergone a percutaneous coronary intervention and are clopidogrel-allergic; and• For short-term use in patients who have had a STEMI. <p>Prasugrel is already funded for these patient groups. PHARMAC is not aware of any new clinical evidence for prasugrel since PTAC’s last review of the product in November 2011. The decision to list ticagrelor would not prevent the widening of access to prasugrel in the future.</p>
The Special Authority criteria could be entirely removed after 6 months of listing.	<p>PHARMAC’s commercial agreement with the supplier would not allow removal of the Special Authority without renegotiation.</p> <p>Because there is a confidential pricing arrangement in the form of annual expenditure caps, any increase in use would disadvantage the supplier.</p>

Theme	Comment
<p>Responders discussed the merits and uncertainties of using genetic testing to target clopidogrel and ticagrelor.</p>	<p>PTAC's advice of February 2012 is that the evidence for using genetic testing to target antiplatelet therapy is not yet sufficient.</p> <p>The Special Authority criteria for ticagrelor will not prevent clinicians from using genetic testing to target treatment in their patients if they wish.</p> <p>This decision also does not prevent PHARMAC from making genetic testing a prerequisite if new clinical evidence is obtained to support that the approach is clinically appropriate and cost-effective.</p>

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.