CONSULTATION

PHARMAC
Pharmaceutical Management Agency

26 March 2013

Proposal to list ticagrelor

PHARMAC is seeking feedback on a proposal to fund the antiplatelet agent ticagrelor (Brilinta) through a provisional agreement with AstraZeneca.

In summary, this proposal would result in ticagrelor being fully funded from 1 June 2013 for patients diagnosed with acute coronary syndromes who meet the Special Authority criteria.

Details of the proposal can be found below and on the following page.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **5pm Friday, 12 April 2013** to:

Sue Anne Yee	Email: sueanne.yee@pharmac.govt.nz
Therapeutic Group Manager	Fax: 04 460 4995
PHARMAC	Post: PO Box 10 254, Wellington 6143

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.

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.

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.

Details of the proposal

- Ticagrelor (Brilinta) would be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 June 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 would be funded subject to the following Special Authority restriction in Section B of the Pharmaceutical Schedule:

Level 9, 40 Mercer Street, PO Box 10-254, Wellington 6143, New Zealand
Phone: 64 4 460 4990 - Fax: 64 4 460 4995 - www.pharmac.govt.nz

Special Authority for subsidy

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

Either:

1 Patient has been diagnosed with ST-elevation acute coronary syndrome in the last 24 hours and fibrinolytic therapy has not been given in the last 24 hours and is not planned; or

2 Both:

2.1 Patient has been diagnosed with non-ST-elevation acute coronary syndrome within the previous 24 hours and fibrinolytic therapy has not been given in the last 24 hours and is not planned; and

2.2 At least two of the following:

(a) ST-segment changes on ECG, indicating ischemia;

(b) a positive test of a biomarker indicating myocardial necrosis; and/or

(c) at least one of the following: age > 60 years, previous coronary event, previous cerebrovascular event, diabetes mellitus, peripheral arterial disease, and/or chronic renal dysfunction.

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

Either:

1 Patient has been diagnosed with ST-elevation acute coronary syndrome in the last 24 hours and fibrinolytic therapy has not been given in the last 24 hours and is not planned; or

2 Both:

2.1 Patient has been diagnosed with non-ST-elevation acute coronary syndrome within the previous 24 hours and fibrinolytic therapy has not been given in the last 24 hours and is not planned; and

2.2 At least two of the following:

(a) ST-segment changes on ECG, indicating ischemia;

(b) a positive test of a biomarker indicating myocardial necrosis; and/or

(c) at least one of the following: age > 60 years, previous coronary event, previous cerebrovascular event, diabetes mellitus, peripheral arterial disease, and/or chronic renal dysfunction.

- Ticagrelor would be subject to indication restrictions in Part II of Section H similar to the Special Authority criteria set out above from 1 July 2013, as part of PHARMAC's work on hospital medicines;

- Confidential pricing arrangements would apply to Brilinta in the form of annual expenditure caps, above which rebates would apply.

Background

Ticagrelor is an antiplatelet agent indicated for the prevention of atherothrombotic events in patients with acute coronary syndromes.

Ticagrelor has been reviewed by PTAC and the Cardiovascular Subcommittee of PTAC. PTAC recommended that it be funded with a low priority for a six month course, restricted by Special Authority criteria (similar to that proposed above) to patients with ST-elevation and non-ST-elevation acute coronary syndromes.

PTAC considered that, based on the clinical evidence, the majority of the benefit from ticagrelor treatment is obtained within the first 6 months; therefore, it would be most cost-effective to restrict ticagrelor to 6 months of treatment. This proposal is for 12 months of

treatment with ticagrelor because concerns about its cost-effectiveness have been addressed via commercial arrangements in this provisional agreement with Astra Zeneca.

Details of PHARMAC's assessment of the application to date, along with minutes from PTAC and Cardiovascular Subcommittee meetings, can be found in PHARMAC's Application Tracker at http://www.pharmac.govt.nz/patients/ApplicationTracker?ProposalId=465.