CONSULTATION

PHARMAC
Pharmaceutical Management Agency

7 August 2014

Nilotinib (Tasigna)

PHARMAC is proposing to list nilotinib (Tasigna) on the Pharmaceutical Schedule for patients with chronic myeloid leukaemia.

- Nilotinib (Tasigna) would be listed in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 November 2014 at the following prices and subsidies (ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Strength	Pack size	Price and subsidy
Nilotinib	Capsule	Tasigna	150 mg	120	$4,680.00
Nilotinib	Capsule	Tasigna	200 mg	120	$6,532.00

- A confidential rebate would apply to Tasigna which would reduce the net price of the treatment.
- Tasigna would have subsidy and delisting protection until 31 October 2017.
- Nilotinib would be listed subject to the following restrictions in Section B and Part II of Section H of the Pharmaceutical Schedule:

Section B

Special Authority for Subsidy
Initial application only from a haematologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1. Patient has a diagnosis of chronic myeloid leukaemia (CML) in blast crisis, accelerated phase, or in chronic phase; and
2. Either:
   2.1. Patient has documented CML treatment failure* with imatinib; or
   2.2. Patient has experienced treatment limiting toxicity with imatinib precluding further treatment with imatinib; and
3. Maximum nilotinib dose of 800 mg/day; and
4. Subsidised for use as monotherapy only.

Notes: *treatment failure as defined by Leukaemia Net Guidelines.

Renewal only from a haematologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1. Lack of treatment failure while on nilotinib as defined by Leukaemia Net Guidelines; and
2. Nilotinib treatment remains appropriate and the patient is benefiting from treatment; and
3. Maximum nilotinib dose of 800 mg/day; and
4. Subsidised for use as monotherapy only.

Part II of Section H

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Initiation
Haematologist
Re-assessment required after 6 months
All of the following:

1. Patient has a diagnosis of chronic myeloid leukaemia (CML) in blast crisis, accelerated phase, or in chronic phase; and
2. Either:

2.1. Patient has documented CML treatment failure* with imatinib; or
2.2. Patient has experienced treatment limiting toxicity with imatinib precluding further treatment with imatinib; and

3. Maximum nilotinib dose of 800 mg/day; and
4. Subsidised for use as monotherapy only.

Notes: *treatment failure as defined by Leukaemia Net Guidelines.

Continuation
Haematologist
Re-assessment required after 6 months
All of the following:

1. Lack of treatment failure while on nilotinib as defined by Leukaemia Net Guidelines; and
2. Nilotinib treatment remains appropriate and the patient is benefiting from treatment; and
3. Maximum nilotinib dose of 800 mg/day; and
4. Subsidised for use as monotherapy only.

- Tasigna when used in the community would be distributed under a direct-to-patient mechanism, which would be managed by PHARMAC and funded by Novartis.

About nilotinib
Nilotinib is an oral tyrosine kinase inhibitor, selective for the oncogene BCR-ABL. Nilotinib is indicated for:

- treatment of adult patients with newly diagnosed chronic phase Philadelphia chromosome positive (Ph +) chronic myeloid leukaemia (CML), and
- treatment of chronic and accelerated phase Ph + CML in adult patients resistant to or intolerant to at least one prior therapy including imatinib.

Currently, two other tyrosine kinase inhibitors are funded for patients with CML, imatinib mesylate (Imatinib-AFT) and dasatinib (Sprycel). Imatinib-AFT is funded without restriction, whereas dasatinib is funded under Special Authority for patients with CML up to a maximum dose of 100 mg/day for patients with chronic phase CML or up to 140 mg/day for accelerated or blast phase CML. The funding of nilotinib as proposed would provide another treatment option for patients who are unable to tolerate imatinib or whose CML disease develops imatinib-resistant mutations.

PTAC and its Cancer Treatments Subcommittee (CaTSoP) have reviewed the funding of nilotinib on a number of occasions. Most recently, at its October 2012 meeting, CaTSoP recommended that nilotinib be funded with high priority for patients intolerant to, or with CML disease resistant to, imatinib or dasatinib. In May 2013 PTAC considered that there would be a significant fiscal risk with funding nilotinib as recommended by CaTSoP given the subjective nature of 'intolerance' criterion. PTAC recommended decline of the application for funding nilotinib on the Pharmaceutical Schedule and considered that it would be more appropriate to assess these patients on a case-by-case basis through the NPPA scheme.

Since March 2013 a total of 12 patients have accessed funded nilotinib through application under the Named Patient Pharmaceutical Assessment (NPPA) Policyat full price. This proposal would be cost saving for these patients and we consider that the proposed net pricing manages the financial risk identified by PTAC as the barrier to Schedule listing.

The minutes for the relevant reviews can be found on the PHARMAC website through the following links:

- http://www.pharmac.govt.nz/patients/ApplicationTracker?ProposalId=478
- http://www.pharmac.govt.nz/patients/ApplicationTracker?ProposalId=189