

6.4 DASATINIB, tablets, 20 mg, 50 mg, 70 mg and 100 mg, Sprycel[®], Bristol Myers Squibb Australia Pty Ltd

1 Purpose of Application

- 1.1 The minor submission sought an amendment to the current first-line PBS restriction for dasatinib in the treatment of patients with chronic myeloid leukaemia (CML) to ensure consistency with the first-line listing for the alternative tyrosine kinase inhibitor (TKI) imatinib, and to make it easier for patients to continue receiving dasatinib whilst they continue to respond to treatment in the first-line setting.

2 Requested listing

- 2.1 The submission sought provision for second and subsequent dasatinib Authority required applications to be made via telephone (as opposed to current written-only applications), consistent with imatinib. Bolded italicised font (below) indicates additional text requested by the submission while deletion to existing text is shown in ~~strike through~~. The suggested changes were consistent with imatinib's current text.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
DASATINIB				
dasatinib 20 mg tablet, 60	1	5	Sprycel	BQ
dasatinib 50 mg tablet, 60	1	5	Sprycel	BQ
dasatinib 70 mg tablet, 60	1	5	Sprycel	BQ
dasatinib 100 mg tablet, 30	1	5	Sprycel	BQ

Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, BCR-ABL tyrosine kinase, and who has a primary diagnosis of chronic myeloid leukaemia.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to dasatinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
- (3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and
- (4) a signed patient acknowledgement form

Authority Required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with dasatinib for the chronic phase of chronic myeloid leukaemia and who has demonstrated either a major cytogenetic response or less than 1% BCR-ABL level in the blood.

First continuing applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) demonstration of a response to treatment as evidenced by either:
 - (a) major cytogenetic response [see Note explaining requirements]; ~~Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided;~~ or
 - (b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements]. ~~Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided.~~

Second and subsequent authority applications for continuing therapy with dasatinib may be made on the telephone by contacting Medicare Australia on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

For more detail on PBAC's view, see section 5 "PBAC outcome"

3 Background

- 3.1 This was the PBAC's first consideration of a submission seeking to allow second and subsequent dasatinib Authority required applications to be made via telephone.

4 Summary of submission

Sponsor hearing

- 4.1 As a minor submission, there was no hearing for this item.

Consumer comments

- 4.2 The PBAC noted that no consumer comments were received for this item.

Basis of request

- 4.3 The submission requested the amendment to the dasatinib restriction on the grounds that:
 - the PBAC has previously found dasatinib to be non-inferior to imatinib in the first-line treatment of CML;
 - both treatments are equally available for the first-line treatment of CML; and
 - dasatinib has been available on the PBS for the treatment of CML since 2007 and therefore its safety profile is well characterised by Australia physicians.
- 4.4 The submission asserted that there is no basis for a difference in restrictions which may encourage the use of imatinib in place of dasatinib. The submission claimed that by normalising the restrictions, physicians can make treatment decisions free of other concerns and focus on achieving optimal outcomes for patients in their care.

For more detail on PBAC's view, see section 5 "PBAC outcome"

Estimated PBS usage & financial implications

- 4.5 The submission stated that the proposed amendment was highly unlikely to change the utilisation of dasatinib individually and of the TKIs as a class.

5 PBAC Outcome

- 5.1 It was the PBAC's view that the existing written-only Authority approval arrangements for second and subsequent dasatinib prescriptions are not a barrier to prescribing dasatinib. The PBAC rejected the request to amend dasatinib's restriction to allow Authority for second and subsequent continuing prescriptions to be sought via telephone or other non-written methods on the basis that drug utilisation data on patient persistence with drug therapy was not presented to support the request. However, the PBAC indicated that it would be prepared to reconsider the requested change if drug utilisation data provided by the sponsor and/or the Drug Utilisation Sub-Committee on patient persistence rates for dasatinib and imatinib indicate no discernable difference.
- 5.2 The PBAC noted the current high PBS expenditure on TKIs in CML and expressed a desire to consider the request in a manner that is informed by drug utilisation data.
- 5.3 The PBAC considered that to justify alignment of the restrictions for dasatinib and imatinib, it may be reasonable to expect that the pattern of usage of dasatinib should be similar to the established pattern for imatinib. In particular, information about persistence on dasatinib, as judged by continuing prescriptions in the years after initiation, would be informative. Confirmation that dasatinib usage in the Australian population of CML patients reflects the data from the randomised trial is also desirable. The PBAC noted that no drug utilisation data had been presented in the submission and considered that such data could provide reassurance that there are no differences in terms of utilisation in clinical practice between the TKIs in CML.
- 5.4 The PBAC noted that this submission is not eligible for an Independent Review as it did not seek to list dasatinib for:
- an entirely different disease or condition than CML for which dasatinib is already subsidised; or
 - an objectively different subtype of CML; or
 - CML but where treatment is targeted at a different population or a different stage of CML.

Outcome:

Rejected

6 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

7 Sponsor's Comment

The sponsor disagrees with the PBAC decision.