

## 12.09 CONTINUING PBS SUPPLY OF IMATINIB

### 1 Purpose of Item

- 1.1 To request an increase in the number of repeats and a change in the authority level from written Authority Required to Authority Required (telephone) for the continuing treatment of rare diseases with imatinib.

### 2 Background

- 2.1 Imatinib is currently PBS listed for the treatment of gastrointestinal stromal tumour, chronic myeloid leukaemia, Philadelphia chromosome positive acute lymphoblastic leukaemia and the following rare diseases:
  - Dermatofibrosarcoma protuberans
  - Chronic eosinophilic leukaemia or Hypereosinophilic syndrome
  - Myelodysplastic or myeloproliferative disorder
  - Aggressive systemic mastocytosis with eosinophilia
- 2.2 At the August 2017 Special Meeting, the PBAC recommended that the authority level of all current imatinib listings other than for CML in the chronic phase be changed to Authority Required (telephone) for initial treatment and Authority Required (streamlined) for continuing treatment phases (August 2017, Web outcomes, Positive Recommendations).

### 3 Current situation

- 3.1 The Department received correspondence from a clinician requesting that the PBAC consider changing the number of repeats and authority level of imatinib continuing treatment for rare diseases, to be consistent with imatinib continuing treatment for other indications such as CML in the chronic phase.
- 3.2 The correspondence noted that the number of repeats for imatinib continuing treatment for rare diseases meant that authority approval was required every three months compared to six months for continuing treatment of CML in the chronic phase. The correspondence further noted that the authority level of imatinib for the continuing treatment of rare diseases was currently Authority Required (streamlined) while the authority level of imatinib for the continuing treatment of CML and other indications was currently Authority Required (telephone).

## **4 PBAC outcome**

- 4.1 The PBAC recommended an increase in the number of repeats of imatinib from two to five for the continuing treatment of rare diseases including dermatofibrosarcoma protuberans, chronic eosinophilic leukaemia or hypereosinophilic syndrome, myelodysplastic or myeloproliferative disorder and aggressive systemic mastocytosis with eosinophilia. Additionally, the PBAC also considered it would be appropriate to extend these changes to imatinib for the initial treatment of rare diseases. In making its decision, the PBAC considered it was appropriate to align the number of repeats of imatinib for the treatment of rare diseases with the number of repeats of imatinib for the treatment of other indications including CML in the chronic phase.
- 4.2 The PBAC noted that an increase in the number of repeats for imatinib listings for the treatment of rare diseases would ease the burden on prescribers.
- 4.3 The PBAC recalled it had already made a recommendation in relation to the authority level for imatinib listings at the August 2017 PBAC meeting. As such, the PBAC reaffirmed its previous recommendation that the authority level for all current imatinib listings other than for CML in the chronic phase be changed to Authority Required (telephone) for initial treatment and Authority Required (streamlined) for continuing treatment phases.

## **5 Recommended listing**

- 5.1 Restrictions to be finalised

## **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.