12.01d ALECTINIB AND CRIZOTINIB Correspondence from Medical Oncology Group of Australia (MOGA)

1 Purpose

1.1 The correspondence from the Medical Oncology Group of Australia (MOGA) requested an increase the number of repeats for alectinib and crizotinib for the treatment of patients with Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) from 1 to 3.

2 Background

2.1 The PBAC recommended listing crizotinib for the treatment of patients with ALK-positive Stage IIIB or Stage IV non-squamous or histology NOS specified NSCLC in November 2015. Crizotinib was listed on the PBS on 1 July 2015. The PBAC recommended extending the listings for crizotinib for patients with metastatic (Stage IV) c-ROS proto-oncogene 1 (ROS1) positive NSCLC at its July 2018 meeting. Both recommended listings were for 1 repeat.

2.2 The PBAC subsequently recommended ceritinib and alectinib for ALK-positive Stage IIIB or Stage IV non-squamous or histology NOS specified NSCLC in November 2016 and July 2017, respectively. Both recommended listings were for 1 repeat.

2.3 The PBAC has not previously considered any requests to increase the number of repeats for crizotinib or ceritinib.

2.4 In March 2019, the PBAC rejected a submission for alectinib that requested a change to the authority level from Authority Required (Telephone) to Authority Required (STREAMLINED) and to increase the number of repeats of alectinib from 1 to 5 (alectinib Public Summary Document, March 2019 PBAC meeting).

- The PBAC noted that 'alectinib was [then] recently listed on the PBS (on 1 January 2018), and longer-term utilisation data was required prior to amending the listing, to ensure use remained cost-effective in the patient population'.
- It considered that 'increasing the repeats from 1 to 5 could inappropriately extend the treatment duration in some patients, with the risk of continuing an ineffective treatment and/or unmanaged toxicity, and that the impact on the cost effectiveness of such extended treatment was unclear'.
- The PBAC noted the recent utilisation data for ALK-inhibitors across all lines of therapy showed a steady increase in uptake, particularly following the listing of alectinib. The PBAC also noted that there was a risk of leakage to other cancers with ALK gene rearrangement that were being identified through tumour whole genome mutation testing, where there was absence of robust evidence of effectiveness and cost-effectiveness. The PBAC advised that an Authority Required (STREAMLINED)

listing would be inappropriate at this time until the ALK-inhibitor market had stabilised.

- The PBAC noted that it would be willing to reconsider a future request for lowering the authority level and increasing repeats for continuing treatment when longer-term PBS utilisation data (at least 24 months) is available for alectinib.
- The PBAC advised that such a request would also need to be considered in the context of changes to other PBS-listed ALK-inhibitors for this condition including ceritinib and crizotinib.

3 Current situation

3.1 The MOGA wrote to PBAC on 23 August 2019 requesting the PBAC consider increasing the number of repeats for both alectinib and crizotinib from 1 to 3 to align with other similar antineoplastic agents for NSCLC such as erlotinib, which are currently PBS listed with 3 repeats.

3.2 The MOGA further noted that an increase in the number of repeats would allow patients more flexibility of follow-up with their oncologists as that appointments are not necessarily required every two months.

4 PBAC Outcome

4.1 The PBAC recommended an increase in the number of repeats for the Authority Required listings for alectinib and crizotinib for Stage IIIB (locally advanced) or Stage IV (metastatic) NSCLC from 1 to 3. The PBAC noted that this change would be consistent with the current listing for erlotinib.

4.2 The PBAC also considered that the change should apply to all ALK inhibitors including ceritinib for Stage IIIB (locally advanced) or Stage IV (metastatic) NSCLC.

4.3 The PBAC further advised that if lorlatinib and brigatinib were recommended for Stage IIIB (locally advanced) or Stage IV (metastatic) NSCLC at its November 2019 meeting, the increase in repeats to 3 should also apply to these recommended listings.

Outcome
Recommended

5 Recommended Listing

5.1 Amend number of repeats to the following Authority Required listings for crizotinib (10322G, 10323H, 11589Y, 11594F), alectinib (11226W) and ceritinib (11056X) as follows:

Suggested additions are in italics and deletions are in strikethrough.

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
ALECTINIB 150 mg capsule, 4 x 56	1	~~1~~*3*	Alecensa	Roche Products Pty Ltd
CRIZOTINIB 200 mg capsule, 60 250 mg capsule, 60	1	~~1~~*3*	Xalkori	Pfizer Australia Pty Ltd
CERITINIB 150 mg capsule, 3x 50	1	~~1~~*3*	Zykadia	Novartis Pharmaceuticals Australia Pty Ltd

6 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

7 Sponsor's Comment

The sponsor had no comment.