Agenda item 11.04

November 2019 MSAC outcomes of relevance to PBAC

1 Purpose of Item

1.1 To request that PBAC note the relevant November 2019 MSAC outcomes for codependent listings, and that PBAC agree that consultations be initiated with affected pharmaceutical companies before recommending changes to the affected PBS restrictions to be coordinated with the MSAC-supported MBS changes.

2 Background

2.1 At the November 2019 MSAC meeting, the following outcomes from the November 2019 PBAC meeting were provided for consideration of the codependent MBS items:

- 5.02 brigatinib (Alunbrig®, Takeda Pharmaceuticals Australia Pty Ltd), recommended for monotherapy treatment of patients with locally advanced (Stage IIIB) or metastatic (Stage IV) anaplastic lymphoma kinase (ALK)-positive non-squamous (NS) or not otherwise specified (NOS) non-small cell lung cancer (NSCLC);
- 6.05 olaparib (Lynparza®, AstraZeneca Pty Ltd), not recommended for the first-line maintenance treatment of ovarian, fallopian tube or primary peritoneal cancer;
- 7.04 ibrutinib (Imbruvica®, Janssen-Cilag Pty Ltd), recommended for first-line treatment of chronic lymphocytic leukaemia/small lymphocytic lymphoma (CLL/SLL) patients with deletion 17p. The PBAC also foreshadowed extending this recommendation to include patients with TP53 mutations and requested that advice from MSAC be sought on the inclusion of this population.

3 Current Situation

3.1 At its November 2019 meeting, the following advice was provided by MSAC for communication to PBAC relevant to the November 2019 PBAC recommendations:

- brigatinib (PBAC 5.02, MSAC 1606) – MSAC supported changes to the related MBS item 73341, with advice for this item descriptor to refer to “ALK inhibitors” rather than list the individual ALK inhibitors;
- ibrutinib (PBAC 7.04, MSAC 1560) – MSAC supported changes to the related MBS item 73343. In relation to the related PBAC request for MSAC advice concerning testing of TP53, MSAC also advised that, at this stage, it does not support an extension of this recommended PBS restriction (or any of the existing PBS restrictions which refer to 17p deletions) to also refer to eligibility being determined via TP53 mutations. In this regard, MSAC advised that genetic

sequencing, rather than genome-wide microarray (see MSAC 1544 below), is the technically preferred testing methodology, but MSAC would need to review the relevant evidence for genetic sequencing before deciding its formal advice on this codependent option.

3.2 At its November 2019 meeting, the following advice was provided by MSAC for communication to PBAC as needing further coordination with PBAC in order to consider modifying the related PBS items:

- olaparib (PBAC 6.05, MSAC 1554) – MSAC supported MBS changes related to adding somatic BRCA mutation testing to help determine eligibility for olaparib's existing second-line PBS restriction;
- ibrutinib, idelalisib and venetoclax (MSAC 1544) – MSAC supported further changes to MBS item 73343 to enable genome-wide microarray to be used as an alternative to FISH in detecting 17p deletions for all existing and recommended PBS restrictions referring to 17p deletions. MSAC further advised that implementing these changes should not impede the implementation of the above advice in relation to ibrutinib (PBAC 7.04).

4 PBAC Outcome

4.1 The PBAC noted the outcomes from the 28 to 29 November 2019 Medical Services Advisory Committee (MSAC) for items considered by PBAC on 6 to 8 November 2019 (brigatinib, olaparib and ibrutinib) and specifically considered the impact of the MSAC advice on PBS listings as below.

Brigatinib

4.2 The PBAC recalled that in November 2019 (item 5.02) it recommended PBS listing of brigatinib for monotherapy treatment of patients with locally advanced (Stage IIIB) or metastatic (Stage IV) anaplastic lymphoma kinase (ALK)-positive non-squamous (NS) or not otherwise specified (NOS) non-small cell lung cancer (NSCLC). The PBAC noted MSAC's November 2019 advice that the related MBS item (73341) refer to "ALK inhibitors" rather than list the individual ALK inhibitors. The PBAC considered that this would not create a barrier for brigatinib or other ALK inhibitor medicines.

Olaparib

4.3 The PBAC recalled that in November 2019 (item 6.05) it did not recommend olaparib for first-line maintenance treatment of ovarian, fallopian tube or primary peritoneal cancer. The PBAC noted that in November 2019, MSAC did not provide advice regarding a first-line listing given that PBAC rejected the submission however, MSAC did support changes to the related MBS items by adding somatic BRCA 1/2 mutation testing to help determine eligibility for the existing second-line PBS restriction.

4.4 The PBAC considered it likely that it would receive a resubmission for olaparib as a first-line treatment, and that it would require advice from MSAC on the inclusion of somatic BRCA mutation testing in this context at that time.

4.5 Given the November 2019 MSAC outcome, the PBAC advised that it would welcome a minor resubmission to its March 2020 meeting to request to broaden the existing PBS listing for second-line treatment to otherwise eligible patients who have tested positive for a somatic BRCA 1/2 mutation. The PBAC advised that this resubmission should estimate the increase in eligible patients and the financial implications to the PBS of this extension to the current listing.

Ibrutinib

4.6 The PBAC recalled that in November 2019 (item 7.04) it recommended PBS listing of ibrutinib, for first-line treatment of chronic lymphocytic leukaemia/small lymphocytic lymphoma (CLL/SLL) in patients with 17p deletion. The PBAC recalled that it also foreshadowed extending this recommendation to list ibrutinib to include patients with TP53 mutations and requested advice from MSAC on this proposed extension.

4.7 The PBAC noted that MSAC did not support extending the eligibility of PBS listings that refer to 17p deletions (including ibrutinib) to include TP53 mutations. The PBAC noted that as a result, patients with TP53 mutations still cannot access PBS subsidy for these medicines, which does not align with treatment guidelines including those from the European Society for Medical Oncology (ESMO)[1], where it is recommended that both 17p deletion and TP53 mutation populations receive first-line ibrutinib or second-line ibrutinib, venetoclax or idelalisib. The PBAC noted that it would need further advice from MSAC regarding the identification of patients with TP53 mutations and that it was interested to further consider this population. The PBAC sought that the Department of Health liaise with relevant stakeholders regarding an applicant to lead an application to MSAC.

Ibrutinib, idelalisib and venetoclax

4.8 The PBAC noted that in November 2019 MSAC had supported changes to MBS item 73343 to enable genome-wide microarray to be used as an alternative to FISH in detecting 17p deletions for all existing and recommended PBS restrictions referring to 17p deletions. The PBAC noted that the advice of MSAC would expand the options for testing, but also limited access to FISH and genome-wide microarray testing to detecting 17p deletions for all related medicines (ibrutinib, idelalisib and venetoclax). The PBAC noted that consultation with relevant sponsors would be required and advised that the addition of genome-wide microarray testing to the MBS

[1] ESMO Guidelines Committee, eUpdate – Chronic Lymphocytic Leukaemia Treatment Recommendations, 27 June 2017, https://www.esmo.org/Guidelines/Haematological-Malignancies/Chronic-Lymphocytic-Leukaemia/eUpdate-Treatment-Recommendations

item should not affect the timing of the implementation of its November 2019 recommendation for ibrutinib in first-line treatment.