| **Drug Name, form(s), strength(s) and Sponsor** | **Drug Type and Use** | **Listing requested by Sponsor / Purpose of Submission** | **PBAC Recommendation** |
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| CRIZOTINIB, 200 mg capsule, 60 and 250 mg capsule, 60  Xalkori®  Pfizer Australia Pty Ltd | Non-small cell lung cancer (NSCLC) | A resubmission to request Authority Required listing for treatment of a patient with Anaplastic Lymphoma Kinase (ALK) positive non-small cell lung cancer (NSCLC) who meets certain criteria. | The PBAC again deferred its consideration of crizotinib to ascertain the applicant’s input on the Committee’s proposed approach to achieve acceptable cost-effectiveness and until such time as MSAC decides to support the corresponding MBS listing of ALK in-situ hydridisation (ISH) testing (and any other associated molecular testing advised by MSAC) for patients with NSCLC. |
|  |  | Sponsor Comment: | Pfizer is committed to working with the PBAC to provide access to crizotinib for patients with ALK-positive NSCLC. |
| PERTUZUMAB, 420 mg/14 mL injection, 1 x 14 mL vial  Perjeta®  Roche Products Pty Limited | Breast Cancer | To request Section 100 (Efficient Funding of Chemotherapy) Authority Required listing of pertuzumab for use in combination with trastuzumab and docetaxel for the treatment of patients with HER2 positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease. | The PBAC deferred making a recommendation on listing pertuzumab to enable it to first consider, establish and accept the cost-effectiveness of trastuzumab for the treatment of metastatic breast cancer, before making a judgement on the cost-effectiveness of all HER2 blocking medicines in metastatic breast cancer, including pertuzumab. |
|  |  | Sponsor Comment: | The sponsor needs to clarify the decision with the PBAC. |
| RANIBIZUMAB, 2.3 mg/0.23 mL, 1 x 0.23 mL vial  Lucentis®  Novartis Pharmaceuticals Australia Pty Ltd | Visual impairment due to diabetic macular oedema and macular oedema secondary to retinal vein occlusion. | Resubmission addressing concerns raised by the PBAC at its November 2013 meeting for the treatment of visual impairment due to diabetic macular oedema (DME) and macular oedema secondary to retinal vein occlusion (RVO). | The PBAC considered that compounded bevacizumab was a relevant comparator because evidence of its current use in patients who would be eligible for PBS-subsidised ranibizumab. In the event of a PBS listing for ranibizumab for the treatment of DME and RVO, prescribers would replace compounded bevacizumab with ranibizumab.  The PBAC noted Departmental advice that, if compounded bevacizumab were to be considered for PBS listing, its pricing for PBS purposes would most likely reflect the approach to pricing already applied to bevacizumab as an oncology medicine through the Efficient Funding of Chemotherapy Program.  The PBAC considered that the presented evidence supported a claim of equivalent effectiveness, but the PBAC would prefer a more robust basis for assessing the comparative effectiveness and safety of ranibizumab and bevacizumab.  The PBAC considered that a comprehensive review of the comparative effectiveness and safety of ranibizumab and bevacizumab would be informative.  The PBAC noted that there are currently many trials either ongoing, or expected to begin enrolling in the near future, which would be applicable to this submission. The PBAC considered that these forthcoming trials may be of relevance and could provide a stronger evidence base.  The PBAC noted the price reduction offered in the submission, but also noted the previously identified issues with the utilities in the modelled economic evaluation had not been rectified in this resubmission. The PBAC did not consider the price reduction sufficient to offset its concerns regarding the economic model. Therefore the PBAC considered it appropriate to continue its deferral from November 2013. |
|  |  | Sponsor Comment: | Novartis disagrees with the decision to utilise an off-label comparator in evaluating the value of ranibizumab for DME and RVO. Novartis is seeking advice regarding this decision and re-evaluating future courses of action. |
| TRASTUZUMAB EMTANSINE, 100 mg injection, 1 x 100 mg vial and 160 mg injection, 1 x 160 mg vial  Kadcyla®  Roche Products Pty Limited | Breast Cancer | The resubmission requests a Section 100 (Efficient Funding of Chemotherapy Drugs program) Authority Required listing for the treatment of patients with HER2 positive metastatic breast cancer (stage IV) who have received prior therapy with trastuzumab and a taxane who meet certain criteria. | The PBAC deferred making a recommendation on listing trastuzumab emtansine to enable it to first consider, establish and accept the cost-effectiveness of trastuzumab for the treatment of metastatic breast cancer, before making a judgement on the cost-effectiveness of all HER2 blocking medicines in metastatic breast cancer, including trastuzumab emtansine. |
|  |  | Sponsor Comment: | The sponsor needs to clarify the decision with the PBAC. |
| ZOSTER VIRUS VACCINE LIVE, 0.65 mL injection, prefilled syringe  Zostavax®  bioCSL (Australia) Pty Ltd | Herpes zoster (shingles) | Resubmission to reinstate the PBAC recommendation for the listing of zoster virus vaccine live (Zostavax) on the National Immunisation Program (NIP) for the vaccination of an ongoing cohort of 60 year olds and a catch-up cohort of 61 to 79 year olds. | The PBAC did not recommend the reinstatement of the previous PBAC recommendation for the listing of zoster virus vaccine in the NIP for 60 year olds and a catch-up cohort of 61-79 year olds, because of unacceptable assumptions in the economic analysis such as the inconsistency between estimates of vaccine efficacy between the trial with its follow up studies and the economic model.  The PBAC noted the Sponsor’s revised proposal seeking the listing of zoster virus vaccine in the National Immunisation Program (NIP) for 70 year olds and a catch-up cohort of 71-79 year olds. The PBAC deferred making a recommendation in relation to this proposal because it was presented to the PBAC without sufficient time to evaluate the changes from the re-submission. |
|  |  | Sponsor Comment: | bioCSL will work with the PBAC to achieve a timely recommendation for listing zoster virus vaccine live (ZOSTAVAX), addressing the unmet public health needto prevent the burden of zoster and post herpetic neuralgia in older Australians |