

ITEMS RECOMMENDED BETWEEN ORDINARY MEETINGS (MARCH 2019 – NOVEMBER 2019)

| SPONSOR, TYPE OF SUBMISSION | DRUG TYPE AND USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|--|-------------------------------|---|--|
| <p>ABEMACICLIB</p> <p>Tablet 50 mg Tablet 100 mg Tablet 150 mg</p> <p>Verzenio®</p> <p>Eli Lilly Australia Pty Ltd</p> <p>New listing (Major Submission)</p> | <p>Advanced breast cancer</p> | <p>To request an Authority Required listing for the treatment of non-premenopausal patients with hormone receptor positive (HR+), human epidermal growth factor receptor-2 negative (HER2-) locally advanced or metastatic breast cancer.</p> | <p>The PBAC recommended the Authority Required listing of abemaciclib for the treatment of non-premenopausal patients with HR+, HER2- advanced breast cancer on a cost minimisation basis to ribociclib and palbociclib. Noting the Therapeutic Goods Administration has registered abemaciclib for this indication, the PBAC was satisfied the remaining outstanding issues relating to the application were satisfactorily resolved.</p> <p>At its March 2019 meeting, the PBAC accepted ribociclib as the main comparator to abemaciclib, which at the time was the only other CDK 4 and 6 inhibitor listed on the PBS for the same indication as abemaciclib. Since the consideration of abemaciclib in March 2019, palbociclib, another CDK 4 and 6 inhibitor, was listed on the PBS on 1 May 2019 for the same indication.</p> <p>The PBAC maintained its view that the cost-minimisation analysis was reasonable when the equi-effective doses are calculated without the duration of therapy being taken into account, in line with the claim of non-inferior comparative effectiveness in terms of progression-free survival.</p> <p>The PBAC considered that abemaciclib should be included in the existing subsidisation caps under the Risk Sharing Arrangement for ribociclib and palbociclib for this indication, and be subject to identical rebates should total expenditure of the three medicines exceed these caps, to ensure there is no new net financial cost to the Government.</p> |