|  |
| --- |
| PBAC Intracycle meetings are held between the main PBAC meetings. Submission items considered by the PBAC at these meetings typically relate to matters arising from previous submissions but can also relate to new medicines.Consumers have the opportunity to provide comments on new medicine submissions. Consumer comments already received in relation to medicines subject to a resubmission have been retained and will be considered. Please note that all items included in this agenda are subject to change at short notice and, when possible, an updated agenda will promptly be published.Pharmaceutical benefits listed in the Schedule fall into three broad categories:*Unrestricted benefits* – have no restrictions on their therapeutic uses; *Restricted benefits* – can only be prescribed for specific therapeutic uses (noted as Restricted benefit); and *Authority required benefits* – Authority required benefits fall into two categories: * *Authority required benefits* require prior approval from Services Australia or the DVA (noted as Authority required)
* *Authority required (STREAMLINED) benefits* do not require prior approval from Services Australia or the DVA but require the recording of a streamlined authority code (noted as Authority required (STREAMLINED)).

Resubmissions are categorised broadly as Standard Re-entry Pathway, Early Resolution Pathway, Early Re-entry Pathway or Facilitated Resolution Pathway. Submission categories and resubmission pathways are outlined in the [Procedure Guidance](https://www.pbs.gov.au/info/industry/listing/listing-steps).   |

| **Drug Name, form(s), strength(s), Sponsor, Submission type**(Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing) | **Drug Type and Use**(What is the drug used to treat?) | **Listing requested by Sponsor / Purpose of Submission**(Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased.) |
| --- | --- | --- |
| AFLIBERCEPTSolution for intravitreal injection 11.34 mg in 100 microlitres (114.3 mg per mL)Eylea®BAYER AUSTRALIA LTD(New PBS listing) | Diabetic macular oedema (DMO) | To request a General Schedule Authority Required (Written) listing for the treatment of patients with visual impairment due to DMO. |
| AFLIBERCEPTSolution for intravitreal injection 11.34 mg in 100 microlitres (114.3 mg per mL)Eylea®BAYER AUSTRALIA LTD(New PBS listing) | Subfoveal choroidal neovascularisation (CNV) secondary to age-related macular degeneration | To request a General Schedule Authority Required (Written) listing for the treatment of visual impairment caused by CNV secondary to age-related macular degeneration. |
| FOSLEVODOPA WITH FOSCARBIDOPASolution for subcutaneous infusion foslevodopa 2400 mg with foscarbidopa 120 mg in 10 mLVyalev®ABBVIE PTY LTD(New PBS listing) | Advanced Parkinson's Disease | To request a General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required (STEAMLINED) listing for the treatment of advanced Parkinson’s disease with severe disabling motor fluctuations not adequately controlled by oral therapy. |
| RESPIRATORY SYNCYTIAL VIRUS VACCINEInjection (0.5mL)Abrysvo®PFIZER AUSTRALIA PTY LTD(New NIP listing) | Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV) | A resubmission requesting a National Immunisation Program (NIP) listing for recombinant syncytial pre-fusion F protein vaccine for the prevention of lower respiratory tract illness caused by RSV in infants from birth through to 6 months of age by the active immunisation of pregnant women. |

|  |  |  |
| --- | --- | --- |
| **Drug Name, form(s), strength(s), Sponsor, Submission type**(Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing) | **Drug Type and Use**(What is the drug used to treat?) | **Listing requested by Sponsor / Purpose of Submission**(Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased.) |
| REVIEW OF ITEMS FOR NURSE PRACTITIONER AND ENDORSED MIDWIFE PRESCRIBING ON THE PHARMACEUTICAL BENEFITS SCHEME Various forms and strengthsVarious brands Various sponsors(Other matters) | Various medicines | To provide the PBAC with an update on the review of PBS prescribing by nurse practitioners and endorsed midwives. |
| UPDATE ON POST-MARKET REVIEW (PMR) WORKPLANDEPARTMENT OF HEALTH AND AGED CARE(Other matters) | N/A | To provide the PBAC with an update on the status of current PMR research projects. |