AUGUST 2019 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
DOLUTEGRAVIR WITH LAMIVUDINE Tablet containing dolutegravir 50 mg (as sodium) with lamivudine 300 mg Dovato® ViiV Healthcare Pty Ltd Deferral of new listing from July 2019 Meeting (Major Submission)	Human immunodeficiency virus (HIV) infection	To request a Section 100 (Highly Specialised Drugs Program - Community Access) Authority Required (STREAMLINED) listing for the treatment of patients with HIV infection.	The PBAC recommended the Authority Required (STREAMLINED), Section 100 (Highly Specialised Drugs (HSD) Program – Community Access listing of a fixed dose combination (FDC) of dolutegravir with lamivudine (Dovato®) for the treatment of HIV in treatment-naïve patients who meet certain conditions. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Dovato would be acceptable if it were cost-minimised against the individual components of the FDC (dolutegravir and lamivudine). The equi-effective doses are one tablet of Dovato® (dolutegravir/lamivudine (50mg/300mg)) once daily and one tablet each of dolutegravir 50mg and lamivudine 300mg once daily. The PBAC recommended a grandfather restriction for patients to transition from concomitant dolutegravir and lamivudine to the fixed dose combination. Patients must have been antiretroviral treatment naïve prior to commencement and still currently on this regimen.
FERRIC DERISOMALTOSE Injection 1000 mg (iron) in 10 mL Injection 500 mg (iron) in 5 mL Monofer® Pfizer Australia Pty Ltd Deferral of new listing from July 2019 Meeting (Minor Submission)	Iron deficiency anaemia	To request an unrestricted benefit listing for a new strength of ferric derisomaltose and to request a change in the maximum quantity and repeats for the currently listed 500 mg strength of ferric derisomaltose.	The PBAC recommended the unrestricted listing of a new form of ferric derisomaltose, 1000 mg/10 mL. The PBAC noted the new form would be covered by the existing financial arrangements for iron deficient anaemia and would be listed at no additional cost to Government. The PBAC also recommended an increase of the maximum quantity to 3 and a reduction in the number of repeats to 0 for the current listing for ferric derisomaltose 500 mg/10 mL solution for injection to allow patients to receive the maximum quantity of 1500 mg per prescription.

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INFLUENZA QUADRIVALENT ADJUVANTED VACCINE Injection 0.5 mL Fluad® Quad Seqirus (Australia) Pty Ltd Deferral of new listing from July 2019 Meeting (Major Submission)	Prevention of seasonal influenza	To request National Immunisation Program (NIP) listing for the prevention of seasonal influenza in patients aged 65 years and over.	The PBAC recommended the listing of adjuvanted quadrivalent influenza vaccine (aQIV, Fluad Quad®) on the National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No.1) (the Determination), for vaccination against influenza in adults aged 65 years and above. Noting the advice in the TGA Delegate's Overview and the Advisory Committee on Vaccines (ACV) consideration of aQIV, the PBAC was satisfied the remaining outstanding issues relating to the application were satisfactorily resolved. The PBAC reiterated its July 2019 advice that it was satisfied that aQIV provides, for adults aged 65 and above, a significant improvement in efficacy over non-adjuvanted QIVs and that it considered that aQIV was cost-effective at the proposed price.
LENALIDOMIDE 5 mg capsule, 14, 21 10 mg capsule, 14, 21 15 mg capsule, 14, 21 25 mg capsule, 14, 21 Revlimid® Celgene Pty Ltd Change to listing (Major Submission)	Multiple myeloma	Submission to request an extension to the Section 100 (Highly Specialised Drug Program) Authority Required listing to include the treatment of patients, in combination with bortezomib and dexamethasone, with newly diagnosed multiple myeloma who are ineligible for a primary stem cell transplant.	The PBAC recommended the listing of lenalidomide in combination with bortezomib and dexamethasone (RVd) for the treatment of patients with newly diagnosed multiple myeloma (NDMM) on the basis that it should be available only under special arrangements under Section 100 – Highly Specialised Drugs Program. The PBAC was satisfied that RVd provides, for some patients, a significant improvement in efficacy over lenalidomide plus dexamethasone (Rd) and bortezomib in combination with melphalan and prednisolone (VMP) and acknowledged the clinical need for triplet combination therapy in the NDMM setting. The PBAC considered that the incremental use of bortezomib was cost-effective at no more than the current net price. The PBAC considered that the incremental use of lenalidomide would be cost-effective if expenditure was capped at no higher than the estimates provided in the submission, implemented through a Risk Sharing Arrangement, together with a price reduction to address the uncertainty in the incremental cost-effectiveness ratio (ICER) of RVd versus bortezomib in combination with melphalan and prednisolone (VMP).