

NOVEMBER 2016 PBAC OUTCOMES – OTHER MATTERS

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>ADALIMUMAB</p> <p>Injection 40 mg in 0.8 mL pre-filled pen Injection 40 mg in 0.8 mL pre-filled syringe</p> <p>Humira®</p> <p>AbbVie Pty Ltd</p> <p>Change to recommended listing</p> <p>(Minor submission)</p>	<p>Ulcerative Colitis (UC)</p>	<p>To request consideration if paediatric patients with moderate to severe UC may swap between PBS-subsidised infliximab and adalimumab.</p>	<p>The PBAC recommended that paediatric patients with moderate to severe UC may swap between infliximab and adalimumab and vice versa, without having to experience a disease flare within the same treatment cycle.</p> <p>The PBAC also recommended that paediatric patients receiving adalimumab or infliximab for moderate to severe UC should not be eligible to trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice within the same treatment cycle. The PBAC recommended that once a patient has either failed or ceased to respond to treatment three times, they are deemed to have completed a treatment cycle and must have, at a minimum, a five year break in PBS-subsidised TNF-alfa antagonist treatment before they are eligible to commence the next treatment cycle.</p>
<p>ANTI-VASCULAR ENDOTHELIAL GROWTH FACTOR (ANTI-VEGF) THERAPIES</p> <p>AFLIBERCEPT 4 mg/0.1 mL injection, 0.1 mL vial Eylea® Bayer Australia Ltd</p> <p>RANIBIZUMAB 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe 2.3 mg/0.23 mL injection, 0.23 mL vial Lucentis® Novartis Pharmaceuticals Australia Pty Limited</p>	<p>Diabetic macular oedema; subfoveal choroidal neovascularisation (due to age-related macular degeneration); central retinal vein occlusion with macular oedema; branch retinal vein occlusion with macular oedema</p>	<p>Correspondence from Vision2020 Australia to request changes to the listings of anti-VEGF therapies to include prescribing by ophthalmology registrars.</p>	<p>The PBAC recommended amending the restrictions of anti-VEGF therapies, including aflibercept, ranibizumab, dexamethasone implant and verteporfin to permit prescribing by ophthalmology registrars and other medical practitioners, in consultation with an ophthalmologist. The PBAC considered that this change may help reduce access barriers to anti-VEGF therapies for indigenous patients and those living in rural and remote areas.</p>

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<p>DEXAMETHASONE 700 microgram implant, 1 Ozurdex® Allergan Australia Pty Limited</p> <p>VERTEPORFIN 15 mg injection, 1 vial Visudyne® Novartis Pharmaceuticals Australia Pty Limited</p> <p>Change to listing (Correspondence)</p>			
<p>FERROUS FUMARATE Tablet 200mg Ferro-tab®</p> <p>FERROUS FUMARATE + FOLIC ACID Ferrous fumarate 310 mg + folic acid 350 microgram tablet Ferro-f-tab®</p> <p>AFT Pharmaceuticals Pty Ltd</p> <p>New listing (Correspondence)</p>	<p>Treatment of a patient identifying as Aboriginal or Torres Strait Islander</p>	<p>To request a Restricted Benefit listing for the treatment of a patients identifying as Aboriginal or Torres Strait Islander.</p>	<p>The PBAC recommended that ferrous fumarate and ferrous fumarate with folic acid be listed on the PBS at the price proposed by the sponsor, in line with the current price of ferrous fumarate and ferrous fumarate with folic acid on the RPBS.</p>
<p>FLUDARABINE 50 mg injection, 1 vial, Fludarabine ACT, Amneal Pharmaceuticals Pty Ltd</p>	<p>B-cell chronic lymphocytic leukaemia (CLL)</p>	<p>To seek the PBAC's advice regarding the restriction level of fludarabine intravenous preparations.</p>	<p>The PBAC recommended that the restriction for fludarabine IV be amended from Authority Required (STREAMLINED) to an unrestricted benefit listing, consistent with fludarabine tablets.</p>

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<p>50 mg/2 mL injection, 5 x 2 mL vials, Fludarabine Ebewe, Sandoz Pty Ltd</p> <p>Change to listing</p> <p>(Correspondence)</p>			
<p>Hepatitis C treatment</p> <p>Gilead Sciences Pty Ltd</p> <p>Change to listing</p> <p>(Correspondence)</p>	<p>Chronic hepatitis C virus (HCV) infection</p>	<p>To request an amendment to the wording of the current “General statement for drugs for the treatment of hepatitis C” on the PBS, in order to align with the most recent best practice for prescribing ledipasvir/sofosbuvir (Harvoni®) and sofosbuvir (Sovaldi®)-based treatment regimens for chronic hepatitis C virus (HCV) infection.</p>	<p>The PBAC recommended the removal of footnotes 4, 5, 6, 7, 8, 9, and 11 from the “General statement for drugs for the treatment of hepatitis C”. The PBAC noted that there are published guidelines for the treatment of HCV and therefore the request was appropriate and clinically justified. The footnotes refer to failure of prior treatment with a peginterferon containing regimen.</p>
<p>VISMODEGIB</p> <p>Capsule 150 mg</p> <p>Erivedge®</p> <p>Roche Products Pty Ltd</p> <p>Change to recommended listing</p> <p>(Minor submission)</p>	<p>Vismodegib is indicated for the treatment of adult patients with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma (BCC) where surgery and/or radiation therapy are not appropriate.</p>	<p>Resubmission to supply new clinical information in relation to the March 2016 PBAC recommendation of vismodegib for the treatment of metastatic or locally advanced BCC.</p>	<p>The PBAC changed the advice that it provided in March 2016 when recommending an Authority Required listing of vismodegib for the treatment of metastatic or locally advanced BCC inappropriate for surgery and curative radiotherapy.</p>