

DECEMBER 2020 PBAC OUTCOMES – 1st TIME DECISIONS NOT TO RECOMMEND

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 pre-filled syringe Injection 40 mg auto-injector</p> <p>Hadlima®</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>Change to listing (Matters outstanding)</p>	<p>Severe Crohn disease; complex refractory fistulising Crohn disease; moderate to severe ulcerative colitis; severe active juvenile idiopathic arthritis; adult patients with a history of juvenile idiopathic arthritis; severe psoriatic arthritis; ankylosing spondylitis; severe chronic plaque psoriasis; severe active rheumatoid arthritis</p>	<p>To request an Authority Required (STREAMLINED) listing for the biosimilar in the continuing treatment phase; to request an Authority Required (Telephone/Online) for the biosimilar in the initial treatment phase; and to request that use of the biosimilar not count as treatment failure.</p> <p>Sponsor's comment:</p>	<p>The PBAC did not recommend changing the authority levels for Hadlima from Authority Required (Written) to Authority Required (Telephone/Online) for initial prescribing, and from Authority Required (Telephone) to Authority Required (STREAMLINED) for first continuing prescribing. For initial prescribing, the PBAC considered that a full assessment (written) is appropriate for Hadlima on the basis that the restrictions are complex and require prescribers to provide detailed clinical information to support the relevant PBS authority application. The PBAC noted that the Department is working with Services Australia to assess the requirements of PBS items which require paper based evidence (such as Hadlima) and will seek the PBAC's advice for change where appropriate.</p> <p>For bDMARD/biologic-naïve patients, the PBAC noted the sponsor's request to have the use of a biosimilar in the first instance not count as a treatment failure as part of a treatment cycle, as one of five agents in rheumatoid arthritis or three agents in ankylosing spondylitis, psoriatic arthritis or chronic plaque psoriasis. The PBAC did not support this request on the basis that a biosimilar medicine is a highly similar version of a reference biological medicine and contemporary clinical evidence does not support that the biosimilar be exempt from the treatment failure rule.</p> <p>MSD is disappointed the PBAC has rejected additional biosimilar uptake drivers proposed to support patient and clinician use of biosimilars which are in line with government policy and the Medicines Australia Strategic Agreement.</p> <p>Existing biosimilar uptake drivers continue to be insufficient to create a viable biosimilar market and deliver the full potential of savings. Urgent action is required to ensure the PBS is set up for success in supporting and benefiting from current and future biosimilars.</p> <p>We remain ready to engage productively in discussions with the government, PBAC and relevant stakeholders to deliver benefits to patients and the health system.</p>

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<p>ETANERCEPT</p> <p>Injection 50 mg in 1 mL single use auto-injector, 4 Injection 50 mg in 1 mL single use pre-filled syringe, 4</p> <p>Brenzys®</p> <p>Merck Sharp & Dohme (Australia) Pty Limited</p> <p>Change to listing (Matters outstanding)</p>	<p>Severe active rheumatoid arthritis Ankylosing spondylitis Severe psoriatic arthritis Severe chronic plaque psoriasis</p>	<p>To request changes to the current initial 1, initial 2 and first continuing restrictions, including changing the restriction level to allow telephone/online authority; and to request that use of the biosimilar not count as treatment failure.</p>	<p>The PBAC did not recommend changing the authority level for initial 1, initial 2 and first continuing prescribing from Authority Required (Written) to Authority Required (Telephone/Online) for Brenzys. The PBAC considered that a full assessment (written) is appropriate for Brenzys on the basis that the restrictions are complex and require prescribers to provide detailed clinical information to support the relevant PBS authority application. The PBAC noted that the Department is working with Services Australia to assess the requirements of PBS items which require paper based evidence (such as Brenzys) and will seek the PBAC's advice for change where appropriate.</p> <p>For bDMARD/biologic-naïve patients, the PBAC noted the sponsor's request for having the use of a biosimilar in the first instance not count as a treatment failure as part of a treatment cycle, as one of five agents in rheumatoid arthritis or three agents in ankylosing spondylitis, psoriatic arthritis or chronic plaque psoriasis. The PBAC did not support this request on the basis that a biosimilar medicine is a highly similar version of a reference biological medicine and contemporary clinical evidence does not support that the biosimilar be exempt from the treatment failure rule.</p>
		<p>Sponsor's comment:</p>	<p>MSD is disappointed the PBAC has rejected additional biosimilar uptake drivers proposed to support patient and clinician use of biosimilars which are in line with government policy and the Medicines Australia Strategic Agreement.</p> <p>Existing biosimilar uptake drivers continue to be insufficient to create a viable biosimilar market and deliver the full potential of savings. Urgent action is required to ensure the PBS is set up for success in supporting and benefiting from current and future biosimilars.</p> <p>We remain ready to engage productively in discussions with the government, PBAC and relevant stakeholders to deliver benefits to patients and the health system.</p>

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<p>LAROTRECTINIB</p> <p>Capsule 25 mg Capsule 100 mg Oral solution 20 mg per mL, 100 mL</p> <p>Vitrakvi®</p> <p>Bayer Australia Ltd</p> <p>New listing (Matters outstanding)</p>	<p>Solid tumours harbouring neurotrophic receptor tyrosine kinase (NTRK) gene fusions</p>	<p>To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of locally advanced or metastatic solid tumours harbouring tropomyosin receptor kinase NTRK gene fusions.</p>	<p>The PBAC did not recommend the listing of larotrectinib for the treatment of patients with <i>NTRK</i> fusion tumours that are either unresectable locally advanced, metastatic, or locally advanced and would otherwise require disfiguring surgery or limb amputation to achieve a complete surgical resection. This decision was made on the basis that the incremental cost-effectiveness ratio was unacceptably high and uncertain at the price proposed.</p> <p>The PBAC reiterated its advice from November 2020 that a sufficient price reduction offer for adult patients with high frequency <i>NTRK</i> fusion tumours and all paediatric patients would be acceptable as a basis to recommend listing for these subgroups. However, any further consideration for adult patients with low <i>NTRK</i> fusion frequency tumours would need to be through a future major resubmission, which includes the forthcoming data from the NAVIGATE and MoST trials to address the uncertainty of the treatment effect of larotrectinib in this patient population, with modified cost-effectiveness analyses incorporating more conservative assumptions and a price reduction.</p>
		<p align="center">Sponsor's comment:</p>	<p>Bayer will continue to work collaboratively with the PBAC, the Department of Health and Federal Government to help ensure that patients with an <i>NTRK</i> fusion cancer in Australia receive access to larotrectinib through the PBS at the earliest opportunity.</p>