

APRIL 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>FILGRASTIM</p> <p>Injection 120 micrograms in 0.2 mL single use pre-filled syringe Injection 300 micrograms in 0.5 mL single use pre-filled syringe Injection 480 micrograms in 0.5 mL single use pre-filled syringe</p> <p>Nivestim®</p> <p>Pfizer Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Chemotherapy-induced neutropenia; Mobilisation of peripheral blood progenitor cells; Assisting bone marrow transplantation; Assisting autologous peripheral blood progenitor cell transplantation; Severe congenital neutropenia; Severe chronic neutropenia; Chronic cyclical neutropenia</p>	<p>To request that the current listings of Nivestim be changed to Authority Required (STREAMLINED) for Section 100 Highly Specialised Drugs (Private Hospital).</p>	<p>The PBAC recommended that based on currently available evidence, the reference biological, Neupogen®, and the three filgrastim biosimilar brands (Nivestim®, Tevagrastim® and Zarzio®) currently PBS listed could be marked as equivalent in the Schedule of Pharmaceutical Benefits ('a' flagged), for the purposes of substitution by the pharmacist at the point of dispensing for all circumstances filgrastim is listed for.</p> <p>In making this recommendation, the PBAC noted there is limited high quality evidence specifically analysing the impact of treatment switching between different filgrastim brands, and further noted most of the evidence available were single arm and/or open-label studies, which often used historical cohorts for the reference biologic. However, the PBAC noted that the evidence in nearly all studies presented concluded similar efficacy and safety with the reference biologic. The PBAC specially noted the Ebbers <i>et al.</i> review presented the most comprehensive summary of evidence of the presented studies, which found no evidence of major safety concerns associated with switching between different filgrastim products. The PBAC also noted there was no data that pointed to major safety concerns associated with switching between different granulocyte colony stimulating factors (G-CSF), and noted the TGA had previously determined the currently PBS-listed filgrastim biosimilars had demonstrated therapeutic equivalence to the reference brand.</p> <p>The PBAC also recalled that when it deferred its decision on this submission at its March 2018 meeting to seeking further information regarding whether the four filgrastim brands currently PBS listed could be marked as equivalent in the Schedule of Pharmaceutical Benefits ('a' flagged) it had advised the following;</p> <ul style="list-style-type: none"> - in principle, support of the application of biosimilar uptake drivers to all biosimilar brands of filgrastim. The PBAC recommended that the Section 100 (Highly Specialised Drugs Program – Private Hospital) listings of filgrastim should be lowered to a streamlined authority; and - that the legislative instrument (LI) forms of the filgrastim brands could be consolidated by removing the brand names that are included as part of the current LI form descriptions.

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<p>OBINUTUZUMAB</p> <p>Solution for I.V. infusion 1000 mg in 40 mL</p> <p>Gazyva®</p> <p>Roche Products Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>CD20 positive follicular lymphoma</p>	<p>To request an Authority Required (STREAMLINED) listing for untreated patients with Stage II bulky or Stage III/IV CD20 positive follicular lymphoma or rituximab-refractory follicular lymphoma.</p>	<p>The PBAC recommended extending the PBS-listing of obinutuzumab to include the treatment of patients with previously untreated advanced follicular lymphoma (Stage II bulky or Stage III/IV) and rituximab-refractory follicular lymphoma. The PBAC recalled that at its March 2018 meeting it had deferred its decision on the submission to allow time for further work to establish a price for treatment with obinutuzumab that could be considered appropriate in both these follicular lymphoma settings and noted that the sponsor had provided additional information:</p> <ul style="list-style-type: none"> • in both settings the financial estimates were updated and a reduced price was proposed; • in the previously untreated setting the proportion of patients eligible for obinutuzumab maintenance was updated; and • in the rituximab-refractory setting the economic model was updated. <p>The PBAC considered that its previous concerns had been adequately addressed.</p> <p>As part of this consideration, the PBAC also recommended extending the PBS-listing of bendamustine to include the treatment of patients with rituximab-refractory follicular lymphoma in combination with obinutuzumab.</p>
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<p>PONATINIB</p> <p>Tablet 15 mg (as hydrochloride), Tablet 45 mg (as hydrochloride),</p> <p>Iclusig®, Specialised Therapeutics Australia Pty Ltd.</p> <p>Other Matter (No sponsor submission)</p>	<p>Acute lymphoblastic leukaemia</p>	<p>To consider advice from the Haematology Society of Australia and New Zealand (HSANZ) in relation to the PBAC’s recommendation at its November 2017 meeting to extend the listing of ponatinib to for relapsed/refractory Ph+ALL to include all patients, regardless of T315I mutation status, who have failed or are intolerant to dasatinib.</p>	<p>The PBAC reiterated its view from the November 2017 meeting that there is a clinical need for treatments of Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) without the T315I mutation. The PBAC considered that ponatinib can be used as a second or third line therapy in the treatment of Ph+ ALL and recommended the listing of ponatinib be extended to include this indication.</p> <p>The PBAC thanked HSANZ for their helpful summary of guidelines and suggested general changes that would better align restrictions for currently listed tyrosine kinase inhibitors (TKIs) for this condition with those guidelines. In regard to the request for the restriction of imatinib in combination with intensive chemotherapy to be broadened to include chemotherapy or corticosteroid therapy, the PBAC agreed to the requested change of an inclusion of corticosteroid therapy in the current restriction wording for imatinib for the Ph+ ALL indication. In regard to the request to allow use of a second generation TKI in the first line setting for Ph+ ALL, the PBAC considered that the evidence did support the use of dasatinib in combination with chemotherapy as an alternative to the use of imatinib plus chemotherapy, but considered that in this setting a price reduction for dasatinib would be required for it to be cost effective. The PBAC asked that the sponsor of dasatinib be invited to make a submission with a proposal on dosing and price for first line therapy in Ph+ ALL, in combination with chemotherapy or corticosteroid therapy.</p>
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