

MARCH 2020 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>DINUTUXIMAB BETA</p> <p>Solution concentrate for I.V. infusion 20 mg in 4.5 mL</p> <p>Qarziba®</p> <p>EUSA Pharma (UK) Ltd</p> <p>New listing (Major Submission)</p>	<p>Neuroblastoma</p>	<p>To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of patients with high risk neuroblastoma or relapsed or refractory neuroblastoma.</p>	<p>Dinutuximab beta was not considered by the PBAC at its March 2020 meeting. During the evaluation process it was determined that dinutuximab beta was likely to be predominantly administered as an inpatient treatment in tertiary public hospitals. This means it would be more appropriately funded jointly by the Commonwealth and the States through the National Health Reform Agreement (NHRA). The submission has been referred to the July 2020 meeting of the Medical Services Advisory Committee, who has assessed all previous applications for funding through the NHRA.</p>
<p>MATTERS RELATING TO PBS UTILISATION REVIEW: PROTON PUMP INHIBITORS (PPIs)</p> <p>ESOMEPRAZOLE, LANSOPRAZOLE, OMEPRAZOLE, PANTOPRAZOLE, RABEPRAZOLE</p> <p>(All current and previously listed brands, including generic versions)</p>	<p>Treatment of gastrointestinal acid related disorders including: gastro-oesophageal reflux disease (GORD), peptic ulcer, hypersecretory conditions including Zollinger-Ellison Syndrome and scleroderma oesophagus.</p>	<p>To provide the PBAC with further correspondence and feedback received by the Department concerning changes to PBS restrictions for PPI medicines, implemented on 1 May 2019.</p> <p>To provide the PBAC with latest available PBS data on the utilisation of PPI medicines post the 1 May 2019 PBS PPI restriction changes.</p>	<p>The PBAC noted the large volume of correspondence from clinicians and patients received by the Department as a result of the implementation of PBS restriction changes to the PPI medicines on 1 May 2019. The majority of complaints received were from patients and prescribers who were unhappy that they could no longer obtain PBS subsidised access to twice daily dosing of standard dose PPIs.</p> <p>The PBAC noted that PBS utilisation data showed a reduction in use of high dose PPIs and an increase in use of low dose PPIs, which is consistent with the intended outcomes of the PBS restriction changes. Overall, the total number of PBS subsidised PPI prescriptions was 5% less for the period 1 May-31 December 2019 compared to the same period in 2018. Analysis of PBS utilisation data for PPI medicines did not indicate a shift to high dose PPIs (esomeprazole 40 mg) or to obtaining greater quantities of low dose PPI medicines for those patients who are now unable to obtain twice daily standard dose PPIs for GORD.</p> <p>The PBAC noted the requested input received from the Gastroenterological Society of Australia (GESA) and the Royal Australian College of General Practitioners (RACGP), which highlighted that GORD is a heterogeneous condition and can be difficult to treat. GESA indicated that in addition to patients with complex GORD symptoms requiring twice daily standard doses of PPIs there is a subset of patients who require long term high dose PPI therapy.</p>

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			<p>The PBAC considered five options presented by the Department; Option 1, to make no further changes and to continue to monitor over 24 months, Options 2 & 3, the proposed PBS restrictions put forward by the GESA, Option 4, the proposed PBS restriction submitted by the RACGP, and Option 5, further prescriber and patient education to support down titration of PPI doses in maintenance therapy of GORD.</p> <p>Overall, the PBAC considered that further changes to PBS restrictions to re-allow increases to maximum quantities of standard dose PPI medicines may send confusing messages to patients and clinicians, and may also risk reversal of improvements in the use of PPIs made since 1 May 2019.</p> <p>Allowing increased quantities for standard dose items for GORD could also discourage clinician/patient attempts to step down therapy. The PBAC acknowledged that rebound symptoms from stepping down PPI therapy are common and can be difficult to manage.</p> <p>The PBAC considered that the options as presented did not provide a suitable path forward. The PBAC requested that the Department draft Authority Required (Telephone) restrictions to include patients with complex GORD requiring twice daily standard or high dose PPI medicines for consideration at a subsequent PBAC meeting.</p>
<p>ONDANSETRON</p> <p>Wafer 4 mg Wafer 8 mg Tablet 4 mg (as hydrochloride dehydrate) Tablet 8 mg (as hydrochloride dehydrate) Tablet (orally disintegrating) 4 mg Tablet (orally disintegrating) 8 mg</p> <p>Various brands</p> <p>Various sponsors</p>	<p>Nausea and vomiting associated with oral chemotherapy being used to treat malignancy</p>	<p>Correspondence from the Medical Oncology Group of Australia (MOGA) to amend the PBS listings for ondansetron tablets, oral disintegrating tablets and wafers indicated for nausea and vomiting associated with oral chemotherapy in line with current PBS listings of ondansetron listings for nausea and vomiting associated with radiotherapy.</p>	<p>The PBAC recommended extending the existing General Schedule listings for ondansetron tablets, orally disintegrating tablets and wafers for the treatment of nausea and vomiting associated with radiotherapy, to also include the treatment of nausea and vomiting associated with oral chemotherapy being used to treat malignancy. The PBAC advised that this change should also apply to the PBS listing for granisetron 2 mg tablets.</p>