

## JULY 2018 PBAC MEETING – OTHER MATTERS

### OTHER MATTERS CONSIDERED BY THE PBAC

#### Matters relating to PBS utilisation review: Proton pump inhibitors (PPIs)

ESOMEPRAZOLE, LANSOPRAZOLE, OMEPRAZOLE, PANTOPRAZOLE, RABEPRAZOLE  
(All current and previously listed brands, including generic versions)

Treatment of gastrointestinal acid related disorders including: gastro-oesophageal reflux disease (GORD), peptic ulcer, hypersecretory conditions including Zollinger-Ellison Syndrome and scleroderma oesophagus.

At its March 2018 meeting the PBAC considered the advice from DUSC on the utilisation patterns of PPIs used in the management of gastrointestinal acid related disorders and recommended that changes to the restriction levels and/or number of repeats of PBS listed PPIs should be reconsidered, along with revision of the wording and terminology of all PPI PBS restrictions at a subsequent meeting.

The PBAC recommended that PBS terminology for PPI strengths change to be consistent with Therapeutic Guidelines and NPS terminology, i.e. high, standard and low dose. The PBAC also recommended changing the wording for all PBS-listed PPI gastric ulcer indications to peptic ulcer, as currently both peptic and gastric ulcer terms appear in PBS restrictions.

The PBAC recommended the following changes to PBS restriction levels:

- Increasing the restriction level of esomeprazole 40mg with 1 repeat from Restricted Benefit to Authority Required (Telephone).
- Changing all standard dose PPIs (esomeprazole 20mg, rabeprazole 20mg, lansoprazole 30mg, omeprazole 20mg and pantoprazole 40mg) from Restricted Benefit to Authority Required (Streamlined).

The PBAC considered that these changes to current restriction levels would create greater awareness amongst prescribers regarding esomeprazole 40mg's higher therapeutic relativity compared to the standard dose PPIs.

The PBAC recommended that the standard dose pantoprazole and rabeprazole PBS items indicated for peptic ulcer with the 2 repeats be reduced to 1 repeat, consistent with all other standard dose PPIs for this indication. The PBAC noted this would also be in line with clinical guidelines which recommend 4-8 weeks of PPI treatment for peptic ulcer.

The PBAC also recommended changes/additions to the clinical criteria for all existing high and standard dose PBS-listed PPIs as follows:

## **JULY 2018 PBAC MEETING – OTHER MATTERS**

- All high dose indications for esomeprazole 40mg 1 and 5 repeat will require trial of standard dose PPI prior to initiation of a high dose PPI.
- All standard dose PPIs with 5 repeats indicated for GORD will have clinical criteria included specifying they are to be used for long-term maintenance of GORD, in a patient inadequately controlled by a low dose PPI.
- For all peptic ulcer indications to require negative H. Pylori testing or failure of eradication therapy before commencement of a standard dose PPI.
- The addition of a new clinical indication - initial and short-term maintenance treatment of symptomatic GORD for standard dose PPIs with 1 repeat.

The PBAC noted this would draw a distinction between patients requiring long-term therapy for GORD (5 repeats) and those indicated for short-term use (1 repeat).

The PBAC did not recommend the proposal for PBS restrictions to include additional clinical criteria stating erosive oesophagitis be confirmed by endoscopy for patients treated with esomeprazole 40mg (1 repeat) and long-term standard dose therapy for GORD (5 repeats), and noted stakeholder concerns that this was clinically not necessary and burdensome for patients. They also did not recommend the addition of treatment criteria to PBS restrictions, which required treatment to be prescribed by a gastroenterologist or in consultation with a gastroenterologist, for all hypersecretory, scleroderma oesophagus and erosive oesophagitis indications. The PBAC suggested PPI utilisation should be reviewed two years post implementation of the above recommendations, and if utilisation has not changed, then these additional restriction measures should be reconsidered.

### **Treatments for Cancer**

The PBAC noted the requests from the Medical Oncology Group of Australia (MOGA) to amend a number of PBS listings for oncology-related listings and provided advice on these requests as follows:

- Pazopanib – Request to amend the current restriction level from Authority Required to Authority Required (STREAMLINED) for all currently listed indications and treatment phases.
  - The PBAC considered the request was reasonable and recommended amending the restriction level of pazopanib for renal cell carcinoma and soft tissue sarcoma (all treatment phases) to a streamlined authority. The PBAC recommended this change could be flowed-on to the listings of sunitinib for renal cell carcinoma.
- Pemetrexed – Request to amend the listings of pemetrexed to an unrestricted benefit.
  - The PBAC noted the price of pemetrexed had dropped substantially in the past several years and recommended amending the listings of pemetrexed to an

## **JULY 2018 PBAC MEETING – OTHER MATTERS**

unrestricted benefit.

- Anti-HER2 therapies (trastuzumab; pertuzumab; trastuzumab emtansine) – Request to remove the requirement for cardiac function testing once every three months.
  - The PBAC noted the requirement for cardiac function testing no longer contributed to determining ongoing patient eligibility for PBS-subsidised therapy and recommended it could be removed from the PBS listings of anti-HER2 therapies.
- Bisphosphonates – Request to permit use of adjuvant bisphosphonates for post-menopausal women with early breast cancer.
  - The PBAC noted the request was to permit use of bisphosphonates for a new population with substantial uncertainties about likely uptake and use, and considered a major submission with full evaluation would be required to progress this request.
- PD-1 inhibitors (pembrolizumab; nivolumab) – Request to remove the requirement for patients with BRAF V600 mutation positive-type melanoma to have progressed following treatment with a BRAF inhibitor prior to trialling a PD-1 inhibitor.
  - The PBAC noted it had established acceptable cost effectiveness of the PD-1 inhibitors in Stage III or Stage IV malignant melanoma on the basis that patients with a BRAF V600 mutation had progressed following treatment with a BRAF inhibitor. The PBAC therefore considered the request would alter the established cost-effectiveness basis on which the PD-1 inhibitors were listed and as such, a major submission with economic model would be required to progress this request.

### **Treatment for Chronic stable plaque type psoriasis vulgaris**

CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE (Gel containing calcipotriol 50 micrograms with betamethasone 500 micrograms (as dipropionate) per g, 60 g, Daivobet 50/500® Gel

Leo Pharma Pty Ltd requested calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 30 g (Daivobet 50/500 gel) be delisted from the PBS. The PBAC had no objection to the delisting of this item, however recommended that the restriction for the 60 g gel be changed to delete the criteria: "Patient must require more than 30 grams of product per month."

### **Treatments with imatinib**

Imatinib is currently PBS listed for the treatment of gastrointestinal stromal tumour, chronic myeloid leukaemia, Philadelphia chromosome positive acute lymphoblastic leukaemia and the following rare diseases:

## **JULY 2018 PBAC MEETING – OTHER MATTERS**

- Dermatofibrosarcoma protuberans
- Chronic eosinophilic leukaemia or Hypereosinophilic syndrome
- Myelodysplastic or myeloproliferative disorder
- Aggressive systemic mastocytosis with eosinophilia

The PBAC recommended an increase in the number of repeats of imatinib from two to five for the treatment of rare diseases including dermatofibrosarcoma protuberans, chronic eosinophilic leukaemia or hypereosinophilic syndrome, myelodysplastic or myeloproliferative disorder and aggressive systemic mastocytosis with eosinophilia. The PBAC recalled that at its August 2017 meeting, it recommended that the authority level for all current imatinib listings other than for chronic myeloid leukaemia in the chronic phase be changed to Authority Required (telephone) for initial treatment and Authority Required (streamlined) for continuing treatment and reaffirmed its recommendation.

### **Treatment for Spinal muscular atrophy**

NUSINERSEN (Solution for injection 12 mg in 5 mL Spinraza™, Biogen Australia Pty Ltd)

The PBAC recommended that the current Section 100 (Highly Specialised Drugs Program) Public Hospital listing for nusinersen be extended to include Section 100 (Highly Specialised Drugs Program) Private Hospitals noting there is a clinical need for prescribing in the private hospital setting.

### **Supply of adrenaline autoinjectors on the PBS**

The PBAC noted that the previous EpiPen® 300 mcg auto-injector shortage has now been resolved. Alternative brands including Adrenaline Mylan and Adrenaline Jr Mylan, which are additional trade names for EpiPen® and EpiPen Jr® auto-injectors, are now PBS listed.

However the PBAC reaffirmed the need for an alternative supplier of adrenaline auto-injectors. The PBAC considered the possibility of a future shortage of adrenaline auto-injectors to be significantly high and requested that the Department continue to investigate options to address this matter.

The PBAC noted that at its March 2018 meeting it had recommended a temporary General Authority Required listing of the EMERADE® brand of adrenaline auto injector, sponsored by Link Medical Products Pty Ltd, to address the shortage supply issue for the PBS listed adrenaline auto injectors that existed at the time. The PBAC also noted that the sponsor had submitted a de-list request within two weeks of being PBS listed.

## **JULY 2018 PBAC MEETING – OTHER MATTERS**

The PBAC recalled that at its July 2016 meeting it had recommended the Adrenaject® brand of adrenaline auto-injector (then named Adrenaline Auto Inject Jr Sun-JV® 150 and Adrenaline Auto Inject Sun-JV® 300), sponsored by SunPharma ANZ Pty Ltd, and that at the March and April 2018 meetings it had deferred a subsequent request from SunPharma to advise that the Adrenaject® brand of adrenaline auto-injector is brand equivalent ('a' flag) to EpiPen® for the purposes of pharmacy level substitution. The PBAC further recalled that it had deferred its decision due to medication safety concerns associated with differences with the administration technique between EpiPen® and Adrenaject® devices. The PBAC considered further information from the sponsor, TGA, Australasian Society of Clinical Immunology and Allergy (ASCIA) and the Department regarding possible measures to support the uptake of an alternative auto injector device and was unable to make a recommendation of brand equivalence on the available information.

The PBAC considered that further exploration of new policy drivers or alternative approaches to creating a viable market for a competitor should be investigated for this critical drug to address the existing barriers to market entry where 'a' flagging is not possible.