| **DRUG, SPONSOR,**  **TYPE OF SUBMISSION** | **DRUG TYPE OR USE** | **LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION** | **PBAC OUTCOME** |
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| Matters relating to PBS utilisation review: Proton Pump Inhibitors (PPIs)  ESOMEPRAZOLE  LANSOPRAZOLE  OMEPRAZOLE  PANTOPRAZOLE  RABEPRAZOLE  (All current and previously listed brands, including generic versions)  Various Sponsors | Treatment of gastrointestinal acid related disorders including: gastro-oesophageal reflux disease (GORD), peptic ulcer, hypersecretory conditions including Zollinger-Ellison Syndrome and scleroderma oesophagus. | To provide the PBAC with feedback received by the Department concerning changes to PBS restrictions for PPI medicines, implemented on 1 May 2019.  To seek the PBAC’s advice on the specific circumstances where the PBS restrictions for standard dose PPI medicines may require amendment to allow twice daily dosing. | The PBAC noted the correspondence from clinicians and patients received by the Department as a result of the implementation of PBS restriction changes to the Proton Pump Inhibitor (PPI) medicines on 1 May 2019. The PBAC also noted the concerns raised and the issues identified and that the feedback represented a small proportion of the numbers of new/original PBS prescriptions for PPIs dispensed annually.  The current PBS PPI restrictions for standard dose PPIs do not allow twice daily dosing. The Australian Therapeutic Guidelines suggest that if high dose therapy is required for symptom therapy in GORD, then the standard dose given twice daily is more effective than a high dose given once daily.  The PBAC expressed concern that under the 1 May 2019 revised restrictions there may be some unintended movement of those patients unable to achieve symptom control with standard dose PPIs prescribed daily to the high dose PPI (esomeprazole 40 mg) taken daily. Conversely, the PBAC was also aware that re-allowing PBS-subsidised increased maximum quantities of standard dose PPIs for GORD risks returning to the situation where high daily doses of PPIs were overused for longer than necessary.  The ability for individuals requiring twice daily dosing to be prescribed increased quantities of low dose PPIs remains an option via telephone authority.  The PBAC did not recommend making further changes to the PBS PPI restrictions which have been in place for less than four months at this time. Assessing changes in the utilisation of PPIs according to dose when more PBS data is available would provide more information for determining if subsequent restriction changes are required. Therefore the PBAC agreed to review the concerns raised on a regular basis and requested that the Department continue to monitor the situation and provide an update to the December 2019 PBAC intra-cycle meeting.  The PBAC also requested that the Department liaise with the Gastroenterological Society of Australia (GESA) and the Royal Australian College of General Practitioners (RACGP) for their input on this matter. |