**PBAC CONSIDERATION OF THE REPORT OF THE DRUG UTILISATION SUB-COMMITTEE**

The PBAC noted utilisation reports with associated stakeholder responses from the July 2022 Drug Utilisation Sub-Committee (DUSC) meeting, which were provided in Items 10.04 and 10.05 of the PBAC Agenda. DUSC minutes relating to these items were provided to the PBAC. The outcomes of the DUSC consideration of these items are available in the [July 2022 DUSC outcome statement](https://www.pbs.gov.au/info/industry/listing/elements/dusc-meetings/dos).

**Proton Pump Inhibitors (PPI) for gastrointestinal acid related disorders**

*Outcome*

PBAC noted PBS data indicated that following the 1 May 2019 PPI restriction changes there was a decrease in the number of high dose PPI prescriptions and a general shift towards the prescribing of lower doses of PPIs. The total number of PBS subsidised PPI prescriptions was 5% less from 1 May-31 December 2019 compared to the same period in 2018.

PBAC noted the overall supply of PPI medicines had remained relatively consistent for rabeprazole, omeprazole and lansoprazole over the reporting period of 2013 Q1 to 2021 Q3. The utilisation of esomeprazole and pantoprazole varied over the period from 2013 to 2021 with an increase in pantoprazole and a decrease in esomeprazole from 2019. PBAC noted pantoprazole and esomeprazole were the most supplied drugs since 2013. Following the 2019 restriction changes, the utilisation of high strength listings decreased from 31,859 prescriptions in 2018 to 11,380 prescriptions in 2021. At the same time, the utilisation of low strength listings increased from 13,720 prescriptions in 2018 to 33,485 prescriptions in 2021. PBAC noted that omeprazole, esomeprazole and pantoprazole were available as over the counter (OTC) medications and that these as well as private prescriptions were not considered therefore utilisation could be higher than seen within this analysis.

PBAC noted more patients starting PPI treatment were prescribed pantoprazole, however total prevalence of patients prescribed esomeprazole was the highest from 2013-2021. The decrease in the utilisation of esomeprazole and increase in pantoprazole in 2019 is likely due to the restriction changes where high dose esomeprazole 40 mg for complex gastro-oesophageal reflux disease (GORD) was restricted to being prescribing by a specialist (gastroenterologist or upper gastrointestinal (GI) surgeon) rather than a decrease in PPI utilisation overall. Pantoprazole was classified as either standard or low dose and had more dispensings from 2019 than any other PPI.

PBAC noted in 2017 there were 145,903 patients starting on a high dose of PPI medication and in 2020 there were significantly less patients initiating (8,026) on high dose PPI. PBAC considered that the restriction changes in 2019 were effective at reducing the number of patients starting on high dose PPI. In 2017 there were 20,309 patients that went from standard to high dose listings and in 2020 there were 5,896 patients starting on a standard dose and shifting to a high dose PPI. In 2020 there was a significant decrease in the number of patients initiating on PPI medication, with 611,154 initiating patients in 2017 compared to 494,347 in 2020. PBAC noted that this could be due to education programs provided to general practitioners, such as from NPS MedicineWise, on the use and appropriate prescribing of PPI medications in addition to the new restrictions. PBAC noted the supply of high dose prescriptions have reduced and low dose prescriptions have increased for PPI, in particular for pantoprazole.

Previous data had shown that the older population were more likely to use PPI long term than any other age group. PBAC noted this was evident within the analysis where patients aged 70-74 years had the highest supply of PPI medication compared to other age groups. This was likely due to this population having multiple co-morbidities (including a high prevalence of GORD) coupled with age-related physiological changes and consumption of multiple medication that cause heartburn therefore requiring medication for symptom management.

PBAC noted that PPI medication and in particular pantoprazole, was still increasing on a yearly basis. The utilisation of the remaining four PPI listings had remained relatively consistent. PBAC considered the growth rate in utilisation for 2020 and 2021 was more than the previous years’ suggesting PPI medications may still be prescribed for longer periods of time than recommended. PBAC considered the reasoning for prescribing for longer periods than recommended may be due to patients not ceasing treatment and new patients receiving prescriptions. PBAC also considered that patients were being prescribed PPI medication in conjunction with anti-inflammatory medication to counteract adverse effects. PBAC noted there could be higher OTC and private prescription data that was not considered.

PBAC noted the Defined Daily Dose (DDD) analysis showed that there has been a reduction in the DDDs for high dose listings. The overall DDDs for all PPIs showed there is an overall reduction in DDDs following the restriction changes. Even though total script utilisation (across all drugs) increased after the May 2019 restriction changes, the total number of DDDs decreased. PBAC considered the restriction changes were successful in decreasing overall utilisation of PPIs by moving patients to lower dose PPIs. However further investigation was warranted at a later time as total DDDs appeared to be on an upward trend and OTC and private prescription data were not included in the analysis.

**Teduglutide for Type III (Chronic) intestinal failure**

*Outcome*

PBAC noted teduglutide utilisation was lower than estimated. The Pre-Sub-Committee Response (PSCR) (p1) considered that the COVID-19 pandemic had affected teduglutide utilisation. The sponsor stated that due to the cancellation of non-elective procedures, adult patients could not initiate treatment as a colonoscopy was required for initiation. Furthermore, the PSCR stated that due to the cancellation of outpatient clinics, specialists were reluctant for patients to initiate treatment due to the complexity of the condition which required close monitoring. PBAC sought consumer input from Parenteral Nutrition Down Under (PNDU) who described factors affecting low teduglutide utilisation including:

* The impact of the COVID-19 pandemic had affected availability of clinical appointments.
* The lack of parenteral nutrition specialists in regional areas where patients must rely on a referral to a gastroenterologist in a major centre.
* Underlying medical conditions can prevent a potential teduglutide patient from initiating treatment.

PBAC noted an additional comment from PNDU who described that not all gastroenterologists, regional and feeder hospitals are familiar with teduglutide. PNDU commented on the need for increased awareness of this drug, and PNDU suggested that the sponsor consider reaching out to clinicians to provide them with further information about teduglutide.

PBAC noted some patients recommenced treatment with teduglutide following a treatment break. Based on data from the sponsor’s patient support program (PSP), the PSCR (p1) stated adult patients treated with teduglutide gain days off and independence from parenteral support (PS). PBAC noted consumer input from PNDU who described patients who have accessed teduglutide have found it to be beneficial and improved their quality of life.

PBAC noted the restriction criteria for treatment failure for adults is defined as, “…an increase in the mean number of days per week in parenteral support (i.e. parenteral nutrition with or without IV fluids) to meet caloric, fluid or electrolyte needs, compared to the most recent authority application.” The PSCR (p2) requested a review of the definition of ‘treatment failure’ in the restriction criteria. The PSCR described the complex clinical situation for patients and commented that “increases in PS volume over the short term are sometimes required.” PBAC agreed with the sponsor and considered that the definition of treatment failure could be changed however PBAC noted that the current restriction was complex and any changes would require further investigation by the Department.