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

The PBAC noted utilisation reports with associated stakeholder responses from the September 2017 Drug Utilisation Sub-Committee (DUSC) meeting, which were provided in Items 10.03 to 10.08 of the PBAC Agenda. DUSC minutes relating to these items were provided to the PBAC. The September 2017 DUSC outcome statement is available here.

5-aminosalicylic acid (5-ASA) medicines for ulcerative colitis

This report was in response to actions arising from the July 2017 consideration of the DUSC ulcerative colitis analysis. Additional data were provided to the PBAC regarding 5-ASA dosing and the proportion of patients supplied mesalazine who received prior sulfasalazine. DUSC concluded the increasing utilisation of 5-ASAs is due to more patients being treated and patients using more mesalazine.

Outcome
The PBAC noted that from 2007 to 2016 the proportion of patients who were previously supplied sulfasalazine at their first mesalazine prescription decreased from 37% to 24%. The PBAC recalled clinical advice from the previous meeting that mesalazine may be used in preference to sulfasalazine because it is better tolerated, requires less intensive monitoring, and has a lower pill burden; or when patients report prior adverse reactions to antibiotics. In addition, sulfasalazine reduces sperm count and the peak age for onset of inflammatory bowel disease coincides with peak reproductive years. The PBAC considered this clinical reasoning was cogent. However, the PBAC noted that there is a substantial cost associated with patients starting with mesalazine instead of sulfasalazine. The PBAC recalled that this was not the setting in which mesalazine was deemed cost-effective. Therefore the PBAC recommended that a price reduction for mesalazine be sought based on the proportion of people who initiate mesalazine without prior sulfasalazine. The number of people would need to be adjusted to account for patients who are truly sulfasalazine-intolerant.

Everolimus and sunitinib use in pancreatic neuroendocrine tumour

This report considered the predicted and actual use of everolimus and sunitinib for metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET) since these medicines were PBS listed for this indication in December 2013 (sunitinib) and April 2015 (everolimus). Actual prescription utilisation and expenditure was less than predicted for both medicines. In contrast, the number of patients treated was more than expected for both medicines. This was explained by the number of prescriptions per patient per year and the overall length of treatment per patient for both medicines being much less than predicted.

Outcome

The PBAC noted the report and recommended no further action.

Lenalidomide for myelodysplastic syndrome

This report considered the predicted and actual use of lenalidomide for myelodysplastic syndrome (MDS) since it was PBS listed for this indication. The actual prescription utilisation was much less than predicted. This was due to both a lower than predicted number of patients treated and lower than predicted number of prescriptions per patient per year.

Outcome
The PBAC considered that the lower than expected use in terms of both prescriptions and patients may indicate that clinicians are skilled in selecting the subgroup of patients who will most benefit from lenalidomide treatment (5q deletion syndrome).
While the PBAC noted that predicted cost savings from reduction of deferasirox use were not realised, there was a reduction in the number of deferasirox users by one third. The PBAC considered that patients who respond to lenalidomide and continue on treatment will reduce their use of deferasirox. The PBAC recommended no further action.

Eculizumab for atypical haemolytic uraemic syndrome

This report considered the predicted and actual use of eculizumab for atypical haemolytic uraemic syndrome (aHUS) since it was PBS listed for this indication in December 2014.

Outcome
The PBAC noted the outcomes of the report; particularly that use was much higher than expected, especially in the first year of listing; and that there were fewer discontinuations and paediatric patients than expected. These factors all contributed to higher than expected costs. The PBAC recalled changes to the restrictions and administrative arrangements from 1 January 2017 and considered that further time is required to before the impact of these changes can be assessed. The PBAC suggested a brief review in 12 months' time to report on the number of initiating and prevalent patients, and the extent of continuation, stopping and restarting therapy. The PBAC requested a more detailed review of eculizumab use when there are 24 months' data post the January 2017 restriction changes.

Nanoparticle albumin-bound paclitaxel for pancreatic cancer

This report considered the predicted and actual use of nanoparticle albumin-bound paclitaxel (nab-paclitaxel) for stage IV (metastatic) adenocarcinoma of the pancreas in the first 24 months of listing from November 2014.

Outcome
The PBAC noted the report and recommended no further action.

Multiple myeloma

This report considered the use of bortezomib, lenalidomide, pomalidomide and thalidomide for the treatment of multiple myeloma. The number of patients with multiple myeloma has increased over time, which may reflect an improving life expectancy of multiple myeloma patients from advances in treatment.

The DUSC noted that new clinical practice guidelines for the treatment of multiple myeloma were released by the Medical Scientific Advisory Group to the Myeloma Foundation of Australia in 2017. The DUSC considered that the introduction of the new guidelines had the potential to change the utilisation of medicines for multiple myeloma in the future.

Outcome
The PBAC noted that use of bortezomib, lenalidomide, pomalidomide and thalidomide for the treatment of multiple myeloma was consistent with restrictions. The PBAC noted the availability of these medicines has improved survival for people with multiple myeloma.

The PBAC considered that the requirement for written authority approval had ensured that prescribing remained in accordance with subsidy criteria. The PBAC acknowledged the high administrative burden for haematologists seeking approval to prescribe these agents.

The PBAC noted that there are combination therapies and maintenance regimens recommended in the Guidelines that are not included the Product Information of the medicines, and are not allowable under the current PBS restrictions. The PBAC considered that the range of regimens used in practice would not be visible from PBAC utilisation data alone.

The PBAC requested advice is sought from relevant clinical groups regarding whether the PBS restrictions for multiple myeloma medicines adequately reflect current clinical practice.