Drug Utilisation Sub-Committee
Outcome Statement 28-29 September 2017

The Drug Utilisation Sub-Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee (PBAC) held its 91st meeting on 28-29 September 2017.

DUSC has a national focus of excellence in collecting, analysing and interpreting data on the utilisation of medicines in Australia for use by the PBAC. Review of the utilisation of medicines is an essential management tool in facilitating the objectives of the National Medicines Policy.

Submissions to the PBAC

DUSC noted that 35 major submissions had been received for the November 2017 meeting of PBAC. DUSC provided detailed advice to the PBAC on projected usage and financial cost for the major submissions where there is high cost, uncertain utilisation, first medicine in class or quality use of medicines concerns. The agenda for the November 2017 PBAC meeting can be found on the PBS website.

Utilisation of PBS Listed Medicines

DUSC regularly examines utilisation of PBS items when there is at least 24 months of prescription data available and where DUSC or the PBAC has highlighted items of interest. When an analysis of utilisation is to be undertaken sponsors are notified, provided with a copy of the report and an opportunity to comment prior to the DUSC meeting. Reviews to be considered by the PBAC are also published in the PBAC meeting agenda.

All reports, Sponsor comments and DUSC assessment of the reports are subsequently provided to the PBAC.

The PBAC is committed to understanding consumer perspectives and integrating them into its consideration of medicines and vaccines. Consumers are able to provide their views about medicine utilisation reviews to the PBAC via a web interface.

Full restrictions for PBS listed medicines are available in the PBS Schedule.

DUSC reviewed the utilisation of the following PBS medicines in September 2017:

5-aminosalicylic acid (5-ASA) dosing

Mesalazine is the most commonly prescribed medicine for ulcerative colitis. DUSC previously found the use of mesalazine was increasing and considered the increasing use may be due to dose escalation. DUSC had requested further analysis to examine this.

A comparison between the number of patients and prescriptions of mesalazine between 2007 and 2016 showed no change in the number of patients taking a 5-ASA for the first time, a 27% increase in the number of patients on 5-ASAs, and a 38% increase in the number of prescriptions. The average amount of mesalazine dispensed per patient per day increased by over 50% between 2007 and 2016.

DUSC concluded the increasing utilisation of 5-ASAs is due to more patients being treated and patients using more mesalazine.

DUSC requested that the report be provided to the PBAC.

Sunitinib and everolimus for metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

DUSC reviewed a predicted versus actual utilisation analysis for sunitinib and everolimus for the treatment of pNET. The actual prescription utilisation and PBS (including Repatriation PBS) 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. DUSC considered that the initial uptake of treatment may have been in patients with more advanced disease which led to shorter duration on therapy than predicted.

DUSC requested that the report be provided to the PBAC.

Lenalidomide for myelodysplastic syndrome (MDS)

DUSC reviewed a predicted versus actual utilisation analysis for lenalidomide for the treatment of MDS. The actual prescription utilisation was much less than predicted. This was due both to a lower than predicted number of patients treated and lower than predicted number of prescriptions per patient per year.

The reason for the number of patients treated being less than predicted was not clear. The PBS restriction specifies that patients should be classified as Low risk or Intermediate-1 (INT-1) according to the International Prognostic Scoring System (IPSS). The estimate of the proportion of MDS patients that were low risk/INT-1 was based on data which may not accurately reflect the overall Australian experience. Also the lower than expected uptake rate may have been a result of patient and prescriber experience of intolerance and adverse events or achievement of less than expected benefit.

The overestimate of the number of prescriptions per patient in the first year of listing may be due to the distribution of patients initiating treatment throughout the year. This analysis found that the number of prescriptions per patient overall was slightly more than expected, but these were spread over a longer period than expected and included breaks in treatment.

The proportion of use of the 5mg capsules was higher than predicted. This result may indicate that adverse events and dose reduction was greater than predicted. The predicted cost savings from reduction of deferasirox use were not realised.

DUSC requested that the report be provided to the PBAC.

Eculizumab for atypical haemolytic uraemic syndrome (aHUS)

Use of eculizumab for atypical haemolytic uraemic syndrome (aHUS) in terms of the number of patients, vials and expenditure was more than double what was predicted in both the first and second years of listing. Since its listing in December 2014, 145 patients have been supplied eculizumab for aHUS at a cost to Government of $71.5 million (to May 2017).

DUSC considered that uncertain estimates of Australian aHUS prevalence at the time of listing may be one factor contributing to higher than expected use of eculizumab. DUSC noted ongoing research regarding whether discontinuation of eculizumab is appropriate. Some patients appear to discontinue eculizumab after around two years of treatment. While PBS data do not provide the reason for stopping treatment, DUSC questioned whether some patients may proceed to transplant.

DUSC recalled the changes that have been made to the restriction criteria, including administrative arrangements, with increasing understanding of Australian clinical practice in using eculizumab for the treatment of aHUS. DUSC acknowledged the important role of expert clinicians in clarifying the clinical place for eculizumab in aHUS. Given use beyond predictions and the high cost of the medicine, DUSC requested a further review of eculizumab use in 12 months' time.

Paclitaxel, nanoparticle albumin-bound, for metastatic adenocarcinoma of the pancreas
Since listing, 3,284 patients have been supplied nanoparticle albumin-bound paclitaxel (nab-paclitaxel) for stage IV (metastatic) adenocarcinoma of the pancreas. The number of patients treated per month had stabilised after 6 months of listing. DUSC noted pancreatic cancer is often not found until it has spread to other organs, and considered it was expected that for most patients there would not be long term or ongoing treatment of nab-paclitaxel for adenocarcinoma of the pancreas.

An analysis of use found the number of patients was very similar to predicted, but the number of vials and prescriptions were lower than predicted. DUSC commented that PBS patients were likely to be older and sicker than the clinical trial patients. DUSC considered that the PBS patients may be more likely to experience drug related toxicity or need longer breaks between treatments.

DUSC requested that the report be provided to the PBAC.

Multiple myeloma
DUSC reviewed the utilisation of four medicines which are used in the management of multiple myeloma, including thalidomide, bortezomib, lenalidomide and pomalidomide. DUSC noted that the number of patients with multiple myeloma had increased over time. This may reflect an improving life expectancy of multiple myeloma patients from advances in the treatment of this condition.

DUSC noted that in most cases, the medicines were being used consistent with their restriction criteria. The restrictions for thalidomide, bortezomib, lenalidomide and pomalidomide require that these medicines cannot be used in combination with each other. There were very few cases found (less than 1%) where more than one medicine was being prescribed on the PBS at a time. Under the restriction for pomalidomide, a patient may only get approval to use this medicine if they have not responded to previous therapy with lenalidomide and also prior therapy with bortezomib. Only a small number of patients were identified as using pomalidomide without first being treated with lenalidomide and bortezomib. Over the data analysis period, which was up to December 2016, lenalidomide was not listed to treat patients with newly diagnosed multiple myeloma. A small proportion of patients did not have a prior medicine before using lenalidomide. DUSC noted that lenalidomide had since listed to treat newly diagnosed patients from 1 February 2017.

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. DUSC considered that the introduction of the new guidelines had the potential to change the utilisation of medicines for multiple myeloma in the future.

DUSC requested that the report be provided to the PBAC.

Upcoming Utilisation Analysis of PBS Listed Medicines

Utilisation of the following medicines and therapeutic areas have been selected for consideration at future DUSC meetings.

Analysis of multiple medicines in a treatment area

- Trastuzumab, trastuzumab emtansine and pertuzumab for HER2 positive metastatic breast cancer
- Ranibizumab and aflibercept for age-related macular degeneration, diabetic macular oedema, central retinal vein occlusion and branch retinal vein occlusion.

Other matters

DUSC reviewed the research report on the utilisation of PBS-listed medicines to treat asthma in children, which was an update of the utilisation analysis and clinical evidence presented in the 2014 post-market review of these medicines.

DUSC noted that, of those children who initiated inhaled corticosteroid (ICS)/long acting beta-antagonists (LABA), 64% had no prior dispensing of ICS or oral corticosteroids, contrary to PBS restrictions. DUSC noted, whilst the 2017 research identified a small reduction in the use of ICS /LABA inhalers, current utilisation was still problematic. DUSC referred to the stepped approach to adjusting asthma medication in children, as outlined in the 2014 Australian Asthma Handbook, and noted that only a small proportion of children with asthma require an ICS/LABA combination.

DUSC considered that an Authority Required Streamlined restriction of ICS/LABA for all ICS/LABA FDCs may help address the above mentioned QUM issues. The DUSC requested that the report be provided to the PBAC.

An outcome statement will be available following each meeting of DUSC. For further information, please contact the DUSC Secretariat at DUSC@health.gov.au.

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Chair
Drug Utilisation Sub-Committee