Drug Utilisation Sub-Committee
Outcome Statement 30 September – 1 October 2021

The Drug Utilisation Sub-Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee (PBAC) held its 103rd meeting on the 30 September – 1 October 2021.

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.

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

Submissions to the PBAC

DUSC noted that eight category 1, 16 category 2, ten standard re-entry submissions and two early re-entry submissions had been received for the November 2021 meeting of PBAC. DUSC provided detailed advice to the PBAC on projected usage and financial cost for the submissions where there was high cost, uncertain utilisation, first medicine in class or quality use of medicines concerns. The agenda for the November 2021 PBAC meeting can be found on the PBS website.

Utilisation of PBS Listed Medicines

DUSC regularly examines utilisation of Pharmaceutical Benefits Scheme (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.

DUSC reviewed the utilisation of the following PBS medicines in October 2021:

Golimumab for the treatment of non-radiographic axial spondyloarthritis

DUSC reviewed the use of golimumab for the treatment of non-radiographic axial spondyloarthritis (nr-axSpA). In the first year of listing, 225 patients were supplied 1,013 prescriptions. In the second year of listing, 413 patients were supplied 2,331 prescriptions. The number of patients and prescriptions in both years of listing was lower than predicted. Other biologic therapies for nr-axSpA, such as certolizumab pegol and secukinumab, were gaining market share.

DUSC requested that the report be provided to the PBAC.

Nivolumab plus Ipilimumab for first-line Stage IV clear cell variant renal cell carcinoma

DUSC reviewed the use of nivolumab plus ipilimumab for first-line Stage IV clear cell variant renal cell carcinoma. Second-line nivolumab was the most common PBS treatment for RCC. In 2021 Q2 there were 1,579 patients receiving PBS treatment for RCC, of these 472 received second-line nivolumab. The second most common treatment was first-line nivolumab, with 312 patients being treated in 2021 Q2.

DUSC considered that the various restriction changes made on 1 September 2019 did not materially impact the utilisation of nivolumab plus ipilimumab. The predicted number of patients in the final agreed estimates were reasonably accurate. Actual prescription numbers for nivolumab were less than predicted. This could be explained by a number of factors including a move from fortnightly to monthly dosing after this was allowed by a restriction change on 1 September 2019 and inaccurate application of PBS item numbers. Further analysis revealed that there was some use of second-line nivolumab treatment items for first-line maintenance treatment and these prescriptions were not counted in the actuals of the predicted versus actual comparison for first-line nivolumab.

DUSC requested that the report be provided to the PBAC.

Pembrolizumab for locally advanced or metastatic urothelial carcinoma

DUSC reviewed the use of pembrolizumab for locally advanced or metastatic urothelial carcinoma. A total of 483 prevalent patients were supplied pembrolizumab in its first year of listing, 680 prevalent patients in Year 2 and 564 prevalent patients in 2021 to the data cut-off date of 31 July 2021. Since its listing, the utilisation of pembrolizumab had increased steadily with up to 50 first initiating (incident) patients per month and the number of prevalent patients was continuing to increase. The total number of prescriptions in Year 1 was 2,392 increasing to 4,283 in Year 2 and in Year 3 to the data cut-off date of 31 July 2021 was 2,942. A Kaplan-Meier analysis of treatment duration, both with breaks and without breaks, indicated that the median time on treatment for patients utilising pembrolizumab was 110 days or 101 days, respectively.

DUSC requested that the report be provided to the PBAC.

Bictegravir+emtricitabine+tenofovir alafenamide and dolutegravir+rilpivirine for HIV and PrEP

DUSC reviewed the use of medications for the treatment of human immunodeficiency virus (HIV) with particular attention to bictegravir+emtricitabine+tenofovir alafenamide (Biktarvy) and dolutegravir+rilpivirine (Juluca).

Since 2014 the overall number of HIV prescriptions had fallen. This was largely due to the reduction in dispensing rates of single medicine products. Whilst single medicine product dispensing rates had fallen, dispensings for combination drug products had increased, with the bictegravir+emtricitabine+tenofovir alafenamide combination product becoming the most commonly prescribed HIV combination drug.

The number of initiating patients supplied Pre-Exposure Prophylaxis (PrEP) had fallen slightly since the listing of tenofovir disoproxil + emtricitabine on the PBS, while the number of prevalent patients had increased since listing. There was a reduction in utilisation between the first and second quarter of 2020, most likely due to the effect of the COVID-19 pandemic on social distancing practices in Australia. The utilisation of PrEP had since returned to its pre-COVID level.

DUSC requested that the report be provided to the PBAC.

Tolvaptan for autosomal dominant polycystic kidney disease

DUSC reviewed the use of tolvaptan for autosomal dominant polycystic kidney disease. In 2019, 362 patients were dispensed 2,323 prescriptions. In 2020, 500 patients were dispensed 4,421

tolvaptan prescriptions. Overall utilisation of tolvaptan was lower than predicted. The most common dosing regimen were patients only supplied the lowest split dose of 45 mg + 15 mg tablets.

DUSC requested that the report be provided to the PBAC.

Upcoming Utilisation Analysis of PBS Listed Medicines

Utilisation of the following medicines has been selected for consideration at future DUSC meetings.

Predicted versus Actual Utilisation Analysis

- Avelumab for the treatment of second-line metastatic Merkel cell carcinoma (mMCC) in patients that have progressed following chemotherapy.

Analysis of single or multiple medicines in a treatment area

- Medicines for the treatment of breast cancer, including a predicted versus actual utilisation analysis of palbociclib.
- Proton pump inhibitors used in the management of gastrointestinal acid related disorders.

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