



Drug Utilisation Sub-Committee Outcome Statement 31 May 2018

The Drug Utilisation Sub-Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee (PBAC) held its 93rd meeting on 31st of May 2018.

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 30 major submissions had been received for the July 2018 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 July 2018 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 May 2018:

Medicines for the treatment of Attention Deficit Hyperactivity Disorder (ADHD)

The utilisation of ADHD medicines increased between 2013 and 2017 in terms of both prescriptions and the number of patients. DUSC expressed concern that the average rate of growth during this period was high. DUSC considered that the growth in the market could be due to improved diagnosis and recognition and continuing use into adulthood, but may also be due to overdiagnosis and overtreatment of ADHD. DUSC also noted that the listing of lisdexamfetamine in 2015 contributed to the market growth. The number of adult patients over the age of 18 years initiating ADHD treatment and the total number of adult patients steadily increased over time.

DUSC noted that while more patients were supplied lisdexamfetamine than predicted in the first two years of listing, these patients received fewer prescriptions per year than anticipated.

DUSC requested that the report be provided to the PBAC.

Medicines for the treatment of melanoma

DUSC reviewed the utilisation of molecularly targeted drugs and immunotherapies listed on the PBS for the treatment of unresectable stage III or metastatic (stage IV) melanoma. The following medicines were included in the analysis: cobimetinib; dabrafenib; ipilimumab; nivolumab; pembrolizumab; trametinib; and vemurafenib. Since 2015, there was a steady growth in utilisation which was mainly attributed to the listing of pembrolizumab. In 2017, a total of 3,792 melanoma patients received at least one of these PBS subsidised medicines.

For the 919 patients who first initiated on PBS therapy between January to June in 2016, the most common therapy was pembrolizumab used first-line (n=517 initiating patients). The second most common drug regimen was dabrafenib plus trametinib used first-line (n=111 initiating patients). Around one-fifth of initiating patients were subsequently supplied another PBS subsidised drug regimen.

DUSC noted that the average age of the PBS population had increased over time. In 2017, the median age was 68 years compared with 63 years in 2014. As the clinical trial populations were generally younger than the PBS population, DUSC considered that the outcomes of the therapies may differ in practice when used in older patients or in patients with poorer performance status. Compared to the clinical trial evidence for progression-free survival times presented in the submissions to the PBAC, the time on second-line therapy was shorter than expected. DUSC considered that this may indicate that patients are not achieving the anticipated benefit.

DUSC requested that the report be provided to the PBAC.

Posaconazole for the treatment and prophylaxis of fungal infections

DUSC reviewed the predicted and actual use of posaconazole for the treatment and prophylaxis of fungal infections since the tablet form listed on the Pharmaceutical Benefits Scheme (PBS) in September 2015.

Following the listing of the tablet formulation, the uptake of posaconazole tablets was rapid and there was a sharp decline in prescriptions for the oral liquid, however the overall use of posaconazole grew substantially. The number of posaconazole prescriptions supplied in 2017 was more than twice the number supplied in 2014 (the calendar year prior to listing of the tablet formulation).

The increasing utilisation of posaconazole seems to be due to a combination of more patients initiating treatment and slightly longer durations of treatment with the tablets compared with the oral liquid. Improved tolerability of the tablet form may be contributing to this trend. DUSC noted that it is not possible to tell from the PBS data alone whether all of the increase in use of posaconazole was appropriate.

DUSC requested the report be provided to the PBAC.

Medicines for the treatment of Age Related Macular Degeneration (AMD), Diabetic Macular Oedema (DMO), Branch Retinal Vein Occlusion (BRVO) and Central Retinal Vein Occlusion (CRVO)

DUSC reviewed the utilisation of ranibizumab, aflibercept and dexamethasone for the treatment of the following eye conditions: age related macular degeneration (AMD), diabetic macular oedema (DMO), branch retinal vein occlusion (BRVO) and central retinal vein occlusion (CRVO).

In 2017:

- 50,964 patients were treated for AMD.
- 11,137 patients were treated for DMO with vascular endothelial growth factor (VEGF) inhibitors, ranibizumab and aflibercept.
- 995 patients were supplied 2,197 dexamethasone implants for DMO. About half of patients supplied dexamethasone in 2017 had previously received ranibizumab or aflibercept.
- 10,781 patients were treated for RVO.

There was a continued growth in the number of treated patients and utilisation of the medicines which was predominantly driven by use in AMD. The market also increased following the extension of listings for ranibizumab and aflibercept to treat DMO and RVO and the listing of dexamethasone for DMO.

There was limited information available to estimate the rate of treatment in both eyes (bilateral treatment). The analysis used the proportion of prescriptions dispensed with a quantity of two to estimate the rate of bilateral treatment. The rate of bilateral treatment was higher for DMO than for AMD, and very low in RVO, consistent with the usual clinical presentations of these diseases.

The number of injections per patient was similar for aflibercept or ranibizumab when used to treat AMD, DMO or RVO. This was consistent with the PBAC's consideration when recommending aflibercept that the price of aflibercept should be based on an injection: injection basis with ranibizumab.

DUSC requested that the report be provided to the PBAC.

Botulinum toxin for spasticity and dystonia

DUSC reviewed the utilisation of botulinum toxin type A supplied through the Pharmaceutical Benefits Scheme (PBS) for the treatment of spasticity in patients with cerebral palsy or following a stroke, and for spasmodic torticollis, blepharospasm and hemifacial spasm.

In 2017, 13,116 patients were treated with PBS subsidised botulinum toxin type A for spasticity or dystonia. The number of patients receiving treatment has increased steadily with an approximate doubling of the number of patients receiving treatment over the past decade. DUSC considered that this growth rate seemed reasonable noting that there have been a number of extensions to PBS listings over this time and an increase in the number of prescribers of botulinum toxin.

The majority of use is for spasmodic torticollis, blepharospasm and hemifacial spasm. Use for each of these indications has been growing, with a higher rate of growth evident for spasmodic torticollis in 2016 and 2017.

The number of patients with cerebral palsy receiving botulinum toxin for upper limb spasticity or foot deformity due to spasticity increased until 2015 and has now stabilised.

In 2017, 742 patients were treated with PBS subsidised botulinum toxin for upper limb spasticity following a stroke and 1,002 prescriptions were dispensed for this indication.

Utilisation of botulinum toxin post-stroke is low in the context of all patients who have experienced a stroke and may have resultant spasticity.

DUSC noted that a large proportion of patients (approximately 20% to 45% depending on indication) only had one prescription supplied. This suggests that many patients who initiate botulinum toxin may not achieve functional improvement or dislike the injections and cease treatment.

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.

Predicted versus Actual Utilisation Analysis

- Bevacizumab for Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer
- Ruxolitinib for the treatment of myelofibrosis
- Eculizumab for atypical haemolytic uraemic syndrome

Analysis of multiple medicines in a treatment area

- Medicines for the treatment of chronic hepatitis C

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