

Drug Utilisation Sub-Committee Outcome Statement 27-28 September 2018

The Drug Utilisation Sub-Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee (PBAC) held its 94th meeting on the 27th and 28th of September 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 November 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 November 2018 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.

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 <u>PBS Schedule</u>.

DUSC reviewed the utilisation of the following PBS medicines in September 2018:

Febuxostat for chronic gout

DUSC compared the predicted and actual utilisation of febuxostat for the treatment of chronic gout in the first 24 months of PBS listing.

The total number of patients supplied febuxostat for the treatment of chronic gout was 2,421 in the first year and 4,881 in the second year of PBS listing. Febuxostat use, in terms of prescriptions and patients, continued to increase since PBS listing. However, substantially fewer patients were supplied febuxostat than predicted. There were also fewer prescriptions dispensed per person than expected. Although uptake from probenecid-treated patients was low, it was similar to predicted. Contrastingly, uptake in the untreated population was much

lower than expected. Recent cardiovascular safety concerns¹ might limit the uptake of febuxostat.

DUSC recalled that the PBAC considered an application from the sponsor in July 2017² which requested the authority level be changed from Authority Required (telephone) to Authority Required (STREAMLINED). The PBAC rejected the request as the restriction appeared to be appropriately targeting therapy to the right people, and there remained a risk that people with allopurinol insufficiency would be prescribed febuxostat although there was a lack of evidence of efficacy and safety in these people. Considering the PBAC outcome, the utilisation data and the safety signals, DUSC considered it would be appropriate for the restriction to remain as Authority Required.

DUSC requested that the report be provided to the PBAC.

Medicines for the treatment of chronic hepatitis C

The utilisation of new generation direct acting antiviral (DAA) medicines for the treatment of chronic hepatitis C was greater than anticipated over the first two years of listing from 1 March 2016. By the end of April 2018, 58,941 individual patients had been dispensed a DAA medicine. The high initial uptake of DAA medicines was mainly due to uptake in patients who avoided interferon-based treatment in anticipation of the new DAAs, which are better at treating hepatitis C and have fewer side effects.

The number of patients starting DAA therapy had stabilised to around 1,200 patients per month compared with around 4,400 initiators per month at the time of listing. The remaining untreated population may include hard-to-reach groups, such as people who inject drugs.

Over the first two years of listing there was more prescribing of DAA medicines by general practitioners in the latter half and less prescribing by specialists. This suggested that more difficult to treat patients were treated early by specialists and general practitioners have become more confident prescribing DAA medicines. Pan-genotypic regimens became the most commonly dispensed DAA regimens, which has simplified prescribing.

DUSC requested that the report be provided to the PBAC.

Ruxolitinib for myelofibrosis

DUSC compared the predicted and actual utilisation of ruxolitinib for myelofibrosis in the first 24 months of PBS listing.

In the first and second years of PBS listing, 861 and 1,082 patients received treatment with ruxolitinib, respectively. This was more patients than predicted in both years. Myelofibrosis can be caused by a range of medical conditions. This made it difficult to accurately predict the number of patients who would be treated with ruxolitinib. Despite more patients receiving treatment than anticipated, there were fewer prescriptions dispensed than expected. The reason for this cannot be determined from the data, but may have been due to patients being less compliant to treatment with ruxolitinib in clinical practice when compared to the

2

¹ White WB, Saag KG, Becker MA, Borer JS, Gorelick PB, Whelton A, et al. Cardiovascular Safety of Febuxostat or Allopurinol in Patients with Gout. N Engl J Med 2018; 378: 1200-1210. DOI: 10.1056/NEJMoa1710895

² July 2017 PBAC public summary document

compliance to treatment observed in clinical trials, or stopping for other reasons, such as adverse drug reactions.

The average dose used in practice was similar to that predicted from clinical trials. Insufficient data were available at the time of reporting to establish the median time on therapy.

DUSC requested the report be provided to the PBAC.

Bevacizumab for ovarian and primary peritoneal cancer

DUSC reviewed the use of bevacizumab which was listed on the PBS for Stage IIIB, IIIC or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer.

Since listing on 1 August 2014, 17,550 prescriptions of bevacizumab were supplied to 1,765 patients under the PBS item codes for epithelial ovarian, fallopian tube, or primary peritoneal cancer. The number of patients starting on bevacizumab each month was steady, and the number of treated patients and dispensed prescriptions has been relatively stable since the beginning of 2016.

The number of initiating patients was close to the number predicted, suggesting that most eligible patients have been able to access bevacizumab. However, the number of prescriptions dispensed was lower than predicted. This was likely because a large proportion of patients had not received the lifetime limit of 18 treatments.

DUSC requested that the report be provided to the PBAC.

Upcoming Utilisation Analysis of PBS Listed Medicines

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

Predicted versus Actual Utilisation Analysis

 Bendamustine for Stage III or IV indolent CD20 positive non-Hodgkins lymphoma and Mantle cell lymphoma

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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