Drug Utilisation Sub-Committee
Outcome Statement 3 June 2016

The Drug Utilisation Sub-Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee (PBAC) held its 87th meeting on 3 June 2016.

DUSC is 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 22 major submissions had been received for the July 2016 meeting of PBAC. DUSC provided detailed advice to the PBAC on projected usage and financial cost for major submissions where there is high cost, uncertain utilisation, first medicine in class or quality use of medicines concerns. The agenda for the July 2016 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.
All reports, Sponsor comments and DUSC consideration of the reports are subsequently provided to the PBAC.

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

DUSC reviewed the utilisation of the following PBS medicines/groups of medicines in June 2016:

Medicines for the treatment of prostate cancer

The total number of patients receiving a medicine subsidised for use in the post-docetaxel metastatic castration resistant prostate cancer (mCRPC) setting had increased substantially from 1,418 patients in 2013 to 4,165 patients in 2015. The number of patients treated was higher than predicted.

The mCPRC treatment paradigm is evolving. The therapy received by patients has changed when comparing patients who initiated a PBS listing for mCRPC in 2013 versus 2015. Not all of the patterns of use were consistent with the current PBS restrictions.

Factors which may be involved in the changing treatment paradigm include expanding treatment options, the regulatory approval for the use of abiraterone and enzalutamide in chemotherapy naïve CRPC patients, and emerging trial evidence investigating hormonal therapies as an alternative or additive to chemotherapy.

The DUSC requested that the report be provided to the PBAC.

Novel oral anticoagulants for prevention of stroke or systemic embolism in non-valvular atrial fibrillation

In the first year of listing, the predicted numbers of patients and prescriptions for novel oral anticoagulants (NOACs) in non-valvular atrial fibrillation (NVAF) were overestimated. In the second year of listing, the actual numbers of patients and prescriptions were both close to predicted. In 2015, there were 1,604,242 PBS subsidised novel oral anticoagulants (NOACs) prescriptions supplied for 188,130 patients for use in non-valvular atrial fibrillation (NVAF). For 72,484 of those patients, it was their first NOAC prescription.

Based on the volume of prescriptions, NOACs contributed to an overall growth in the anticoagulant market since their listing on the PBS for NVAF. The use of warfarin has declined since then.

The DUSC requested that the report be provided to the PBAC.

Medicines for the treatment of glaucoma

The number of PBS and RPBS prescriptions for glaucoma medicines increased steadily between 2004 and 2015. Over 4.3 million prescriptions were supplied in 2015. Supply of fixed dose combination (FDC) products as a proportion of all glaucoma medicines increased from 9% in 2004 to 30% in 2015; there were over one million more FDC prescriptions supplied in 2015 than in 2004. While the majority of patients who start a glaucoma medicine do so with a single ingredient medicine, a small, but increasing group of people appear to be starting treatment with a FDC product.

DUSC suggested that advice be sought from the Royal Australian and New Zealand College of Ophthalmologists (RANZCO) and Optometry Australia on the current treatment algorithm for glaucoma, including pharmacological and non-pharmacological treatments, changes in the surrogate outcome of intraocular pressure targets, and use of outcomes such as visual field loss.

The DUSC requested that the report be provided to the PBAC.

Biological disease-modifying anti-rheumatic drugs (bDMARDs) for ankylosing spondylitis

DUSC reviewed the use of bDMARDs for ankylosing spondylitis at the February 2016 meeting and found high and increasing utilisation of these medicines. A further analysis showed that the male:female ratio for patients treated with PBS subsidised bDMARDS for AS is declining over time. In 2005, the ratio was approximately 3.5:1 for initiating and prevalent patients. The ratios for initiating and prevalent patients decreased to 1.2:1 and 2:1 respectively by 2015.

The declining gender ratio may in part be accounted for by increased or earlier diagnosis, and increased rates of treatment with bDMARDs for women with AS. The changing M:F ratio is broadly consistent with changing prevalence reported in the literature. DUSC considered that the changing ratios in the literature are generally the result of inclusion of patients with non-radiographic spondyloarthropathies. This group is not eligible for PBS subsidised bDMARD

treatment which requires evidence of Stage II sacroiliitis orradiographic changes on xray. DUSC noted that some differences in the reporting of sacroiliac joint involvement may occur.

The DUSC requested that comment be sought from the Australian Rheumatology Association and 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

- Rifaximin for prevention of hepatic encephalopathy.
- Imatinib for gastrointestinal stromal tumour (extension of treatment duration from 1 to 3 years).
- Mifepristone and misoprostol for the termination of pregnancy.
- Denosumab for osteoporosis, in the context of the overall osteoporosis market.
- Voriconazole for prophylaxis of fungal infections in certain high risk patients, in the context of the overall antifungal market.
- Erlotinib and gefitinib for Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer.
- Everolimus for tuberous sclerosis complex.
- Botulinum Toxin Type A for treatment of adult patients with chronic migraine. The Botox program became prescription based from 1 September 2015. The utilisation review will be undertaken when there is at least one year of prescription data available.

Analysis of multiple medicines in a treatment area

- Antipsychotic medicines, including a review of quetiapine following the change to the available number of repeats of the 25 mg strength.
- Testosterone, to assess the impact on utilisation of changes to the restrictions implemented in April 2015.
- PBS medicines prescribed by authorised dental practitioners.
- Medicines for the treatment of diabetes.

DUSC noted that a large number of utilisation reviews have been proposed and requested that the reviews of antipsychotics, testosterone and osteoporosis be prioritised for the September 2016 DUSC meeting.

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