



Drug Utilisation Sub-Committee Outcome Statement 5 June 2014

The Drug Utilisation Sub-Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee (PBAC) held its 81st meeting on 5 June 2014.

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 29 major submissions had been received for the July 2014 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 2014 PBAC meeting can be found at <http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/agenda/07-2014>

Utilisation of PBS Listed Medicines

DUSC regularly examines utilisation of PBS items when there is at least 12 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.

Full restrictions for PBS listed medicines are available in the PBS Schedule (www.pbs.gov.au)

DUSC reviewed the utilisation of the following PBS medicines/groups of medicines in June 2014:

Biological Treatments (adalimumab, etanercept, infliximab and ustekinumab) for Severe Chronic Plaque Psoriasis

The number of patients on treatment has increased steadily since the first product was listed in 2006. During 2013, almost 3,500 patients accessed biological disease modifying anti-rheumatic drugs (bDMARDs) for psoriasis, with adalimumab and ustekinumab being most commonly used. The majority of patients who start treatment continue long term.

DUSC considered that there may be some eligible patients with severe refractory disease not treated with bDMARDs if they do not have access to a dermatologist. DUSC also considered there may be some use of subsidised bDMARDs for less severe psoriasis, outside of the PBS criteria, although this cannot be ascertained from prescription data.

DUSC requested that the report be provided to the PBAC for information.

Pazopanib and Sunitinib for Renal Cell Carcinoma

Approximately 500 patients start treatment with either sunitinib or pazopanib for renal cell cancer each year. Pazopanib has had rapid uptake since listing on 1 October 2012. DUSC considered that there was no additional growth in the total renal cell cancer market due to the listing of pazopanib.

DUSC requested that the report be provided to the PBAC for information.

Medicines for Bone Metastases due to Breast and Prostate Cancer

The use of drugs such as zoledronic acid in patients with advanced cancers was fairly stable until 2011. Denosumab has had rapid uptake since listing in December 2011, and by late 2013 had become the most commonly prescribed medicine for bone metastases due to breast or prostate cancer. DUSC noted that denosumab was recommended on the basis of superior efficacy compared with zoledronic acid, and that there has been growth of the overall bone metastases market since denosumab was listed.

Omalizumab for Severe Allergic Asthma

The utilisation of omalizumab in the first two years of PBS listing continued to be lower than expected. The majority of patients who start omalizumab continue treatment. DUSC considered that ongoing lower uptake of omalizumab was most likely due to reluctance to use oral corticosteroids at relatively high dose for at least 6 weeks due to concerns about tolerability and a likely overestimation of the eligible population.

DUSC requested that the report be provided to the PBAC for information.

Ocular Lubricants for Dry Eye Syndrome

DUSC noted that expenditure across the ocular lubricants has been gradually increasing whilst prescription numbers are fairly stable. DUSC noted that there are currently a large number of ocular lubricant products listed on the PBS with a variety of prices. DUSC noted that current prices vary between ocular lubricants that contain a preservative and the ocular lubricants that are preservative free. The gradual increase in prescribing of the more expensive single dose unit products is likely to explain the small gradual increase in expenditure on ocular lubricants despite stable prescription numbers.

DUSC requested that the report be provided to the PBAC for information.

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 12 or 24 months after listing

- Pregabalin for neuropathic pain
- Exenatide for type 2 diabetes
- Ezetimibe and simvastatin fixed dose combination for hypercholesterolaemia
- Rivaroxaban for acute DVT treatment and prevention. DUSC requested that the analysis include rivaroxaban, apixaban and dabigatran for all PBS listed indications other than atrial fibrillation
- Tobramycin and mannitol for cystic fibrosis. DUSC requested that the analysis also include dornase alfa.

Analysis of multiple medicines in a treatment area

- Antibiotics
- Hepatitis B medicines

Other Matters

Palliative Care

DUSC noted the low utilisation of the medicines listed in the Palliative Care Schedule and considered they remain underutilised. DUSC considered this may present a quality use of medicines issue. The low utilisation of the medicines listed in the Palliative Care Schedule may

be due in part to the dual listing of many of the Palliative Care Schedule medicines in the General Schedule. DUSC requested that options for increasing the appropriate utilisation of medicines listed in the Palliative Care Schedule be considered.

Predicted Versus Actual Analyses

DUSC recommend that Predicted versus Actual analyses be conducted routinely at 24 months instead of 12 and 24 months as is currently the case. DUSC noted that this does not preclude 12 month analyses being requested where appropriate.

This change was recommended because:

- the methodology used for DUSC analysis has evolved allowing improved insight and understanding of how medicines are used in practice. Utilisation reports now frequently include patient level analyses to assess treatment pathways and co-administered therapies, and assess variables such as duration of therapy and frequency of resupply. These enhanced analyses generally require more than 12 months of data for meaningful interpretation.
- management of PBS expenditure through Risk Sharing Arrangements (where the Government and the Sponsor agree to share the risk of a drug costing more to the PBS than expected) has expanded. At 30 June 2006, there were 34 risk share pricing agreement in place or being developed. In comparison, at 30 June 2013 there were 76 deeds of agreement in place or in development. As more risk sharing arrangements are in place and management of RSAs occurs on an annual basis, efficient use of resources is directed towards greater focus on 24 month analyses.

In accordance with usual DUSC policy, predicted versus actual utilisation analyses can be undertaken outside of the standard timeframe when needed. For example if there is concern about safety or where new therapies change the treatment algorithm and an utilisation review would be informative.

Membership

The Chair noted that Dr Alasdair Millar will not be continuing on DUSC and thanked him for his valuable contribution to the work of DUSC.

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

Professor Geoff McColl
Chair
Drug Utilisation Sub-Committee