



Drug Utilisation Sub-Committee Outcome Statement 7-8 February 2013

The Drug Utilisation Sub-Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee (PBAC) held its 77th meeting on 7-8 February 2013.

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 26 major submissions had been received for the March 2013 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 March 2013 PBAC meeting can be found at <http://www.pbs.gov.au/industry/listing/elements/pbac-meetings/pdf/pbac-meeting-agenda-march-2013.pdf>

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 February 2013:

Adalimumab and infliximab for complex refractory fistulising Crohn disease

DUSC considered that the utilisation of adalimumab and infliximab for fistulising Crohn disease was within the range expected for the first year of listing. DUSC noted that any future analyses of the utilisation of tumor necrosis factor alpha inhibitors for Crohn disease would be enhanced by assessing rates of continuation and discontinuation. DUSC requested that the report be provided to the PBAC for information.

Adapalene with benzoyl peroxide gel for severe acne vulgaris

DUSC considered that the utilisation of adapalene with benzoyl peroxide gel was within the range predicted for the first year of PBS listing. DUSC noted a low proportion of patients move from acute treatment to maintenance treatment, and that this could be due to poor adherence and persistence to therapy, or possible use outside the restriction in patients with less severe acne.

Omalizumab for severe allergic asthma

Utilisation of omalizumab during the first year of listing on the PBS was lower than expected. DUSC considered that the following factors may have contributed to the lower use: the eligible population may have been overestimated at the time of listing, the complexity and administrative requirements of the restriction may be a barrier to prescribing, and there may be reluctance to use long-term corticosteroids, due to adverse effects, in order to meet prerequisites for omalizumab. DUSC requested that the utilisation report be provided to the PBAC and that consideration be given to reconvening the stakeholder group identified pre-listing to assist in understanding factors impacting on utilisation. DUSC also requested a subsequent review when 24 months' data is available.

Diabetes

At the October 2012 meeting DUSC reviewed the utilisation of medicines for newly diagnosed type 2 diabetes and suggested further analyses be conducted to better understand treatment in patients who require more intensive management

(<http://www.pbs.gov.au/info/industry/listing/elements/dusc-meetings/dos>).

At the February 2013 meeting, DUSC further examined the utilisation of medicines for type 2 diabetes in a prevalent population of patients. DUSC noted a large proportion of prescriptions supplied through the PBS for the dipeptidyl peptidase-4 inhibitors ('gliptins') do not meet the criteria for PBS subsidy. DUSC also noted some prescribing of exenatide, rosiglitazone and pioglitazone is outside of the PBS restrictions. DUSC considered that the PBS restrictions do not align with recent clinical guidelines and the perceived place of newer medicines for type 2 diabetes in practice. The data suggests that gliptins may be viewed as an alternate therapy to sulfonylureas, rather than being reserved for patients who cannot take a sulphonylurea. As gliptins are much more costly than sulphonylureas, use outside of the current PBS restrictions is unlikely to be cost-effective at the current prices. DUSC requested that the report be provided to the PBAC and NPS MedicineWise. The utilisation findings will contribute to the Post Market Review of Products Used in the Management of Diabetes

(<http://www.pbs.gov.au/info/reviews/diabetes>).

Quantity of insulin supplied on PBS prescriptions

An analysis of PBS prescription data showed that nearly all prescriptions of insulin are for the PBS maximum quantity of five packs, despite there being a wide range in the insulin dosing needs of individual patients. DUSC noted that it is essential that patients have an adequate supply of insulin, but quantities supplied may not always be appropriate and there may be some wastage. DUSC requested that the distribution of insulin doses be investigated from additional data sources. There may be a need for an education campaign if further analysis indicates that there is wastage is occurring.

Antipsychotics

DUSC had previously raised concern that the utilisation of PBS listed antipsychotics is growing at a higher than expected rate, and requested additional analyses to better understand utilisation (<http://www.pbs.gov.au/industry/listing/elements/dusc-meetings/dos/dusc-dos-oct-2012-v2.0.pdf>).

Analysis of PBS prescription data demonstrated that there is high and inappropriate utilisation of antipsychotics in the elderly. Of particular note, quetiapine and olanzapine are prescribed at a rate in the elderly inconsistent with the age specific prevalence of bipolar disease and schizophrenia (the PBS listed indications) revealing substantial use outside of the restriction. Risperidone is the only antipsychotic medicine that has specifically been assessed by the PBAC

for efficacy, safety and cost-effectiveness in an elderly population with behavioural and psychological symptoms of dementia.

The prescription data also indicate some use of antipsychotics in very young patients. DUSC requested further investigation to verify this use. The prescription data also suggest possible use of antipsychotics for non-PBS subsidised indications in middle-aged adults and DUSC requested supportive analysis to clarify how these medicines are being used in practice.

Overall, DUSC considered that the increasing use of antipsychotics, without a proportionate increase in the prevalence of the PBS listed indications, is a major Quality Use of Medicines problem. There appears to be substantial use beyond the restrictions, for indications or populations where there has been no formal assessment of efficacy, safety and cost-effectiveness. DUSC requested that the utilisation report be provided to PBAC and to NPS MedicineWise particularly raising the high and inappropriate use of antipsychotics in the elderly.

HIV

DUSC considered that increasing utilisation of medicines for the treatment of HIV infection aligns with the increasing population of people living with HIV, increased awareness and diagnosis, lifelong therapy, and government endorsed treatment targets. From the available data, DUSC considered that prescribing is in accordance with clinical guidelines. DUSC noted that a number of fixed dose combination products are available, and as combination therapy is indicated for first and subsequent lines of therapy, considered these products to be an important aspect of the management of HIV infection. DUSC also noted a shift in best practice recommendations towards earlier initiation of treatment. The current PBS restrictions for most products limit use to patients with a CD4 count less than 500 per cubic millimetre or symptomatic HIV. DUSC referred the report 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.

Utilisation Analysis 12 months after PBS listing

- Dutasteride and dutasteride with tamsulosin for benign prostatic hyperplasia;
- Cetuximab for colorectal cancer. DUSC suggested that the review should also include bevacizumab.
- Tobramycin solution for inhalation for management of *Pseudomonas aeruginosa* infection in patients with cystic fibrosis.
- Imatinib extension to listing to include adjuvant treatment of gastrointestinal stromal tumour following complete resection of primary tumour.

Analysis of multiple medicines in a treatment area

- Opioids
In considering the 1 August 2011 listing of a new brand of fentanyl transdermal patch, DUSC suggested a class review of opioid medicines to consider the under co-payment data. This review would be considered by DUSC at the October 2013 meeting at the earliest, so as to incorporate at least 12 months of full under co-payment data collection.
- Antimycotics, including fluconazole powder for suspension
When fluconazole powder for suspension was recommended for listing, the PBAC requested that the DUSC review utilisation to ensure that prescribing is consistent with PBS-subsidised indications. The review will include all antimycotics for systemic use.

Other Matters

Fixed Dose Combination Products

DUSC has noted emerging trends with some fixed dose combination (FDC) products such as a higher proportion of patients commencing de novo and FDCs increasing the market rather than substituting within current markets. DUSC requested further analysis be conducted to assess utilisation of FDCs in practice. Cardiovascular system and antiglaucoma FDCs were identified as classes with numerous FDC products and were prioritised for review. DUSC suggested that patterns of use in practice should be compared to the basis of PBAC recommendation and FDC criteria in the PBAC guidelines. The analyses will assist in determining if a review of PBAC guidelines relating to FDCs is required. DUSC will consider FDCs at future meetings and provide advice to the Economic Sub-Committee, PBAC Guidelines Working Group and the PBAC where necessary.

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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