Drug Utilisation Sub-Committee
Outcome Statement 2 February 2017

The Drug Utilisation Sub-Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee (PBAC) held its 89th meeting on 2 February 2017.

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 22 major submissions had been received for the March 2017 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 March 2017 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/groups of medicines in February 2017:

Imatinib for the adjuvant treatment of gastrointestinal stromal tumour

In the first two years from the extension to the PBS listing on 1 December 2013, 449 patients were supplied imatinib for the adjuvant treatment of gastrointestinal stromal tumour (GIST). This was similar to the number of patients estimated by the submission. However, there were fewer prescriptions than predicted, which may have been due to discontinuation from side effects or treatment failures. The total net expenditure was higher than expected, likely due to the higher than predicted average daily dose.

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

Everolimus for tuberous sclerosis complex
Since 1 December 2013, 322 patients were supplied everolimus for tuberous sclerosis complex (TSC). The use of the lower doses (2.5 mg and 5 mg) was more than expected which may relate to the tolerability of the drug. Use in children could also be a factor. The treated population had declined over time. Possible causes for this were considered to be drug tolerability and potential use prior to surgical resection which involves shorter durations of treatment.

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

Everolimus for metastatic breast cancer
In the first two years of PBS listing, 1,813 patients were treated with everolimus for metastatic breast cancer. This was fewer patients than predicted at the time of listing. These patients were also on treatment with everolimus for a shorter time period than expected, which resulted in a lower number of prescriptions than predicted. This may be because the estimates did not account for treatment breaks.

DUSC noted that although the recommended starting dose is 10 mg, people over 70 years were more commonly started on the lower 5 mg strength. DUSC also noted that the proportion of people on 10 mg to 5 mg is reducing over time. DUSC considered there may be a variety of clinical reasons for this other than age, such as reducing the impact of drug interactions or adverse effects.

The use of everolimus was consistent with its restriction with the majority of patients receiving a prior supply of letrozole or anastrozole. The expenditure on everolimus was less than predicted over its first two years of listing.

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

Iron, as ferric carboxymaltose
There was substantial growth in the total parenteral iron market after ferric carboxymaltose (FCM) was PBS listed. There were 87,433 patients treated with parenteral iron in the year FCM was PBS listed, increasing to 130,000 the year after. There were 69,460 FCM prescriptions supplied in the first year of PBS listing (June 2014 to May 2015) and 125,887 prescriptions supplied in the second year (June 2015 to May 2016). The use of FCM has been substantially higher than predicted.

The DUSC considered that the use of FCM has been higher than predicted due to a range of factors including:

- an underestimate of the size of the baseline treated and untreated IDA populations
- a likely shift from the oral market for patients inadequately treated with oral iron due to dose-related gastrointestinal effects or for those people where FCM is preferred due to ease of administration or other factors
- higher than expected uptake, which may be a result of increased general awareness of IDA and education around the detection and management of IDA.

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

Medicines for the treatment of diabetes

There have been a number of new medicines and extensions to PBS listings of medicines for diabetes since the last DUSC review in February 2013. Key changes have included the listing of sodium-glucose co-transporter 2 inhibitors (flozins), extensions to listings for the dipeptidyl peptidase 4 inhibitors (gliptins) and the glucagon-like peptide-1 (GLP-1) analogue, and the availability of additional fixed dose combination products.

The use of diabetes medicines continues to grow. DUSC considered the high use of metformin monotherapy reflects its place in guidelines as first line therapy. The use of flozins and gliptins are increasing. Overall use of diabetes medicines appears generally within PBS restrictions. There is some concern about use outside of restrictions, such as possible use of flozins, gliptins or exenatide as monotherapy and regimens containing combinations of flozins, gliptins or exenatide. DUSC recognised that while there may be a clinical place or need for these regimens in practice, such use has not been assessed by the PBAC and is not subsidised through the PBS. The DUSC and stakeholders also expressed concern regarding the complexities of the PBS restrictions for diabetes medicines.

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

Tyrosine kinase inhibitors for non-small cell lung cancer

In 2014, 598 patients commenced erlotinib or gefitinib for first-line treatment of Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) harbouring EGFR mutations. In 2015, 347 patients commenced first-line erlotinib or gefitinib therapy. The number of people receiving first line TKIs was similar to expected in 2014 and lower than expected in 2015.

Median length on tyrosine kinase inhibitor treatment for first-line use was similar to predicted. The observed prevalence of EGFR mutations (17.9%) was similar to predicted (15%).

A small proportion of patients (7.4%) initiating TKI therapy in 2014 had supplies of chemotherapy between supplies of TKI, indicating use beyond progression or in combination with chemotherapy, which is outside the PBS restriction. If immunotherapies become available for use subsequent to tyrosine kinase inhibitors this pattern of use may change.

The 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.

Analysis of multiple medicines in a treatment area

- Medicines for the treatment of Crohn disease.

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