PBAC CONSIDERATION OF THE REPORT OF THE DRUG UTILISATION SUB-COMMITTEE

The PBAC noted utilisation reports with associated stakeholder responses from the February 2016 Drug Utilisation Sub-Committee (DUSC) meeting, which were provided in items 10.03 to 10.07 of the PBAC Agenda. DUSC Minutes relating to these items were provided to the PBAC. The February 2016 DUSC Outcome Statement is available here.

BIOLOGICAL DISEASE-MODIFYING ANTI-RHEUMATIC DRUGS (bDMARDS) FOR ANKYLOSING SPONDYLITIS

The PBAC noted that the use of bDMARDs to treat ankylosing spondylitis was increasing with no sign of a slowing in the growth of this market; despite it being more than 10 years since the first PBS listing of a bDMARD for this condition. The PBAC noted that a higher proportion of patients receive a second authority approval (indicating response according to the PBS criteria) than predicted. The PBAC recalled that similar trends have been observed for bDMARDs used in other PBS listed indications. The PBAC also noted that most patients remain on bDMARD therapy for long periods of time and that only a small proportion of patients are approaching the end of a PBS treatment cycle where a 5-year break in PBS-subsidised bDMARD therapy is required before they are eligible to commence the next cycle.

The PBAC noted that while ankylosing spondylitis is more common in males, the ratio of male to female patients in recent PBS use is approximately one to one. The PBAC considered it unlikely that these patterns of use would occur if these medicines were being used in the intended population according to the restriction. The PBAC commented that despite the imaging requirements there may be use in other spondyloarthropathies where the evidence has not been evaluated by the committee.

The PBAC requested that advice is sought from the Australian Rheumatology Association to better understand how bDMARDs are being used in ankylosing spondylitis and other spondyloarthropathies.

BIOLOGICAL DISEASE-MODIFYING ANTI-RHEUMATIC DRUGS (bDMARDS) FOR PSORIATIC ARTHRITIS

The PBAC noted that up to 17% of patients may not have received methotrexate and either leflunomide or sulfasalazine prior to commencing biological disease modifying anti-rheumatic drug (bDMARD) therapy; as is required to meet the PBS restriction. While some of this would be accounted for by contraindications to traditional disease modifying anti-rheumatic drugs (DMARDs), the PBAC considered this raised an issue of potential non-compliance with the restriction in some patients. The PBAC requested that advice be sought from the Australian Rheumatology Association regarding whether there is a trend toward use of bDMARDs earlier in the treatment algorithm, whether there is an unmet need for bDMARDs in the management of psoriatic arthritis and whether practice is changing ahead of clinical guidelines.

SMOKING CESSATION

The PBAC considered that PBS-subsidised smoking cessation therapies form part of the suite of options available to assist people in quitting smoking.

The PBAC noted that changing the PBS restriction for nicotine replacement therapy (NRT) from Authority Required to Authority Required (STREAMLINED) did not significantly impact the utilisation trends of R/PBS smoking cessation therapies.

The PBAC raised concerns regarding the reported adverse effects of varenicline and recent safety advice from the Therapeutic Goods Administration[1]. The PBAC also noted that information available on the comparative efficacy of smoking cessation therapies continues to evolve. An article published in January 2016 by the Journal of the American Medical Association[2] found no significant differences in biochemically confirmed rates of smoking abstinence between varenicline and NRT.

TICAGRELOR FOR ACUTE CORONARY SYNDROME

The PBAC noted the analysis of predicted versus actual use found the uptake of ticagrelor within the acute coronary syndrome market was underestimated in the early years of listing but overestimated in later years.

The PBAC noted from the length of treatment analysis the majority of people have stopped taking ticagrelor one year after initiation but that about 20% of patients remain on treatment for two years or more. The PBAC noted that the PBS restriction allows clinical discretion by not limiting the subsidised duration of therapy. However, the PBAC noted that the benefits and harms need to be weighed up for longer durations of treatment, particularly the risk of increased bleeds with ongoing dual therapy.

The PBAC recommended that use of ticagrelor and other medicines for acute coronary syndrome be reviewed again in 12-24 months; including an update of the length on treatment analysis and an assessment of the impact of longer durations of treatment on the costs to government.

MEDICINES FOR ALZHEIMER DISEASE

A post-market review was undertaken for anti-dementia medicines in 2012. The PBAC recalled that a key outcome of the post-market review was to simplify the PBS continuing restriction to better align with clinical use. The PBAC noted that as there has been no substantial change in the proportion of people continuing on anti-dementia therapies that alignment has been achieved.

The PBAC noted that the price reduction arising from the post-market review re-established the cost-effectiveness of these medicines. However, the PBAC agreed with DUSC that quality use of medicines concerns remain, including that some patients continue on anti-dementia medicines for long periods of time where there may be little or no benefit, and co-administration of anticholinergic medicines with cholinesterase inhibitors.

[1] Therapeutic Goods Administration. Medicines Safety Update Volume 7 Number 1, February 2016 (website here).

[2] Baker et al. Effects of nicotine patch vs varenicline vs combination nicotine replacement therapy on smoking cessation at 26 weeks. JAMA January 2016 (315): 4

The PBAC noted there are new anti-dementia agents in the research pipeline. The PBAC considered it worthwhile to gather information from experts in the field in advance of these drugs seeking subsidisation.