

**NOVEMBER 2021 PBAC MEETING – CONSIDERATION OF THE REPORT OF THE
DRUG UTILISATION SUB-COMMITTEE**

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

The PBAC noted utilisation reports with associated stakeholder responses from the October 2021 Drug Utilisation Sub-Committee (DUSC) meeting, which were provided in Items 10.04, 10.05, 10.06, 10.07, 10.08 and 10.09 of the PBAC Agenda. DUSC minutes relating to these items were provided to the PBAC. The outcomes of the DUSC consideration of these items are available in the [October 2021 DUSC outcome statement](#).

Golimumab for non-radiographic axial spondylarthritis (nr-axSpA)

Outcome

PBAC noted that new medicines such as certolizumab pegol may have gained some of the expected market of golimumab for nr-axSpA, however this use does not account for the large difference between the predicted and actual treated patients.

Overall, the submission estimated there were approximately 30,000 to 35,000 nr-axSpA prevalent patients per year, and that 18.9% of these would be eligible under the PBS restriction. It was unclear why the predicted and actual number of treated patients were so different. PBAC noted that the number of prevalent patients for golimumab, certolizumab and secukinumab in total was closer to what was predicted for golimumab. PBAC commented that difficulties accessing a rheumatologist, understanding and awareness of the disease and reluctance to initiate biologics to be factors influencing the lower than expected uptake.

PBAC noted concerns from Arthritis Australia on the issue of adolescents being diagnosed with non-radiographic axial spondylarthritis however these patients were ineligible under the current restriction. PBAC recommended removing the age specificity from the restriction and considered specialists' would continue to prescribe appropriately.

Review of antiretrovirals for HIV/Pre-Exposure Prophylaxis (PrEP) and utilisation of Biktarvy[®] and Juluca[®]

Outcome

PBAC noted that overall costs and patients for HIV medications were stable with incremental growth. PBAC noted that there was a shift to combination preparations with combination triple therapy exceeding expectations while single and double therapy preparations were decreasing.

PBAC noted that standard practice was to use triple drug therapy and considered that Biktarvy's increased utilisation was due to a decreased pill burden, and improved adverse drug event profiles.

PBAC noted that PrEP had increasing utilisation in year 2 of listing and was reducing in year 3. PBAC noted that the COVID-19 pandemic may have impacted PrEP use with this decline seen in 2020 and also noted there may be a shift to on-demand use in this population.

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PBAC noted the NPS analysis of PBS data found that new HIV diagnoses in patients at least 31 days following PrEP initiation was higher than the incidence seen in the EPIC-NSW study.

PBAC noted the data presented by NPS on prescriber type and caseloads of practices specialising in this area.

Nivolumab and ipilimumab for renal cell carcinoma (RCC)

Outcome

PBAC noted that the actual prescription numbers for nivolumab were less than predicted. PBAC noted that this may be due to a shift to less frequent dosing where a restriction change was made in September 2019 to allow an increase to monthly dosing from fortnightly. PBAC noted an overestimation of the average length of treatment which more closely reflected the duration seen in the pivotal trials.

PBAC noted that there was evidence of an incorrect allocation of authority codes which may have contributed to the reduced number of prescriptions and that the way the listings are presented on the PBS website may be contributing to the incorrect selection of authority item codes. In the case of nivolumab there are 30 different item codes each with their own restriction text which would make it difficult to find the correct item code for prescribers. PBAC requested the department to consider if it was possible to improve the website for all prescribers.

PBAC noted that the restriction change to Authority Required (STREAMLINED) in maintenance therapy did not result in increased utilisation.

Pembrolizumab for urothelial carcinoma

Outcome

PBAC noted that prior to recommending pembrolizumab there was a concern of leakage into first-line use and for treatment beyond progression. PBAC noted that the utilisation data indicated that leakage into first-line appeared to be less than ten percent and treatment duration was shorter than expected.

PBAC noted sponsor comments regarding mean time on treatment, increased use due to the pandemic and the request to include all stage bladder cancer patients in forming population estimates. PBAC considered that the shorter duration likely reflects the older frailer population seen in practice compared to the trial data. PBAC agreed with the sponsor that increased use during the pandemic was likely driven by changes in clinical guidance recommending immunotherapy with longer durations between treatment than chemotherapy. PBAC considered that including all stage bladder cancer patients in the estimates was not appropriate as including patients with regional or distant bladder cancer did not meet face validity for localised or metastatic urothelial cancer.

Tolvaptan for autosomal dominant polycystic kidney disease

Outcome

PBAC considered the boxed warning, mandatory prescriber education, effectiveness of lifestyle modifications (i.e. non-pharmacologic interventions) and the treatment associated side effects as possible reasons for low tolvaptan utilisation. PBAC considered clinical input which described the initial authority process for tolvaptan was

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laborious which may also explain the low uptake. Clinical input was also provided regarding regional differences in prescribing and PBAC noted a possible Quality Use of Medicines issue which may require further investigation.

Naltrexone for alcohol use disorder

Outcome

PBAC noted that acamprosate was changed to an Authority Required (STREAMLINED) listing in September 2015 however naltrexone was currently Authority Required.

PBAC requested further information from the department to consider if an alteration to the listing for naltrexone to Authority Required (STREAMLINED) would be appropriate.