3 October 2017

Pharmaceutical Benefits Advisory Committee
PBAC Secretariat – MDP 952
Department of Health and Ageing
GPO Box 9848
Canberra ACT 2601

RE: November 2017 PBAC Meeting

Dear PBAC

SHPA is the national professional organisation for over 4,400 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system. SHPA is committed to facilitating the safe and effective use of medicines, which is the core business of pharmacists, especially in hospitals. SHPA members lead the Pharmacy Departments at 29 of the principal referral hospitals in Australia, as well as the vast majority of both Public Acute A and Public Acute B hospitals.

SHPA notes that in the November 2017 PBAC Meeting, PBAC is considering a minor submission for blinatumomab supply arrangements be amended from Section 100 (Efficient Funding of Chemotherapy) to Section 100 (Highly Specialised Drugs). SHPA has the following remarks with respect to the PBS listing of blinatumomab.

Administration of blinatumomab requiring inpatient hospitalisation

SHPA believes blinatumomab should receive PBS subsidy for inpatient administration. This would ameliorate the inequity of patient access to blinatumomab for patients who cannot afford private hospital cover.

Blinatumomab's PBS listing notes state that:

"According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 9 days of the first cycle…

… Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting."

Public hospitals are unable to fund this expensive treatment without PBS support, resulting in patients missing out on treatment for acute lymphoblastic leukaemia altogether in public hospitals. A patient must then utilise a private hospital to access PBS subsidised blinatumomab at their own cost, however a minimum of nine days private hospital oncology admission is too cost prohibitive for many for it to be a viable solution.

A solution is possible with a provision allowing for PBS-subsidised blinatumomab to be administered to inpatients, similar to the listing of eculizumab for the treatment of Atypical haemolytic uraemic syndrome (aHUS). Eculizumab is regarded as one of the most expensive medicines in the world, with a cost of $500,000 per patient per year on the PBS. This PBS listing recognises the specialised nature of eculizumab to treat aHUS, and the necessity of an inpatient admission to monitor appropriately. Hence, the PBAC has established a precedent for situations where patient safety and quality use of medicines requires a PBS listed medicines to be provided to inpatients in order to provide equitable access.

Adequate reimbursement for chemotherapy preparation fees

SHPA believes reimbursement for chemotherapy preparation should be commensurate with what is practically required. At present, the Efficient Funding for Chemotherapy allows for payment of one preparation fee per chemotherapy cycle. However, many chemotherapy medicines, such as blinatumomab, require more than one preparation across treatment cycles that last for weeks. It is estimated that a four-week blinatomumab treatment cycle would require, at minimum, four preparations, however, only one fee is paid. This means that hospitals are forced to absorb the chemotherapy preparation costs each time treatment cycles require more than preparation.

Adequate reimbursement for number of vials required for treatment cycles

SHPA believes that the reimbursement for the supply of blinatumomab 38.5µg vials should be sufficient to cover the entire treatment cycles. SHPA appreciates that blinatumomab has been listed under Section 100 (Efficient Funding for Chemotherapy) due to the volumetric nature of its dosing, similar to many other chemotherapy medicines.

However, the methods used to calculate the maximum number of blinatumomab vials allowable for reimbursement do not factor in the practicalities of the extractability of blinatumomab from the vials. It appears in determining the maximum number of vials to be reimbursed, PBAC has simply calculated the dose of blinatumomab required per cycle, and divided by 38.5µg to elucidate the number of vials required. This does not take into the practicalities of only an average of 35µg being able to be extracted from each blinatumomab, or that Cycle 1 requires a lower dose 9µg for the first seven days of treatment.

SHPA understands that the PBS currently subsidises 17 vials of blinatumomab 38.5µg in Cycle 1 and 21 vials in Cycles 2 and beyond, however in practical terms, 24 vials in Cycle 1 and 28 vials in Cycles 2 and beyond are required for full treatment. The current shortfall means that health services must fund the residual number of vials required, which places an unnecessary and unforeseen burden on health services and their patients, and can potentially result in patients not receiving full treatment, thus leading to treatment failure.

If you have any queries or would like to discuss our submission further, please do not hesitate to contact Johanna de Wever, General Manager, Advocacy and Leadership on jdewever@shpa.org.au or (03) 9486 0177.

Yours sincerely,

Kristin Michaels
Chief Executive Officer