PCPA
PRIVATE CANCER PHYSICIANS OF AUSTRALIA

15th June 2014

Submission to The Australian Government Post-Market Review of Authority Required PBS Listings.

This submission is made by the Private Cancer Physicians of Australia, the peak representative body for Medical Oncologists and Clinical Haematologists working in private practice in Australia. The PCPA is dedicated to the improvement of health care for all cancer patients with a particular focus on ensuring high quality cancer care in the private sector in Australia. Since 2008, the PCPA has been actively engaged with the Australian Government in reforms to the supply of chemotherapy services in Australia. Those reforms have been based around providing safe and cost effective chemotherapy and supportive care agents to patients with cancer. The President of PCPA in 2008, was a lead negotiator in the professional and consumer group response to the initial reform plans and that effort has continued with the PCPA and Medical Oncology Group of Australia making a joint submission to the review of chemotherapy funding arrangements in 2013. Throughout this process, it has been understood that there is a significant regulatory burden placed on prescribing Oncologists by the PBS Authority system. In 2013, there were 447 phone or complex authority required listings on the PBS. It is recognised that the majority of those listings affect Medical Oncologists and Clinical Haematologists in their day-to-day work. This burden has significant implications for the work of Pharmacists and hospitals and has a significant economic impact on the delivery of cancer care.

In initial discussions in 2008 and 2009, with the Minister for Health, The Honorable Nicola Roxon, it was recognised on all sides that the burden of Authority Prescriptions was a significant issue that needed to be part of the overall reform process. Indeed, it was then identified that one full-time equivalent session per week was being used by most full-time Medical Oncologists in Australia complying with the authority required system. As a result of those negotiations, there has been significant reform and a useful reduction in the number of agents requiring phone authority and the introduction of more widespread streamlining. However, as we will discuss in our submission, there are significant disparities between public and private requirements that remain and there is a significant burden attached to a small, but very important number of supportive care drugs. Of particular concern has been the increased reliance on Complex Authority required listings where the burden of documentation has become increasingly onerous.

The other area of particular interest to private hospitals in Australia is the development of appropriate E-prescribing programs and systems to equal those that are already existent in many public hospitals and which have been trialled for several years in a small number of private hospitals. We contend that these systems provide an ultimate solution to the Authority Prescription system with a very clear ability to provide quality assurance and to provide an economically efficient method of prescribing. Equally, they provide the unique opportunity to obtain nationwide data on chemotherapy usage and outcomes which are of particular relevance given the discussions around the importance of post-approval outcome collection in assessing the appropriateness of drug re-imbursement under the PBS.

We would highlight the following concerns:
1. The persisting significant authority burden for Medical Oncologists and Clinical Haematologists.

There remain a number of important chemotherapy agents which are not streamlined. We provide a list of those medications, but also would point out that there are important supportive care medications which are used frequently by Oncologists and for which authorities are required. These include G-CSF or Filgrastim, Pegfilgrastim, and Bisphosphonates which are given commonly in myeloma, lymphoma and breast cancer settings, in addition to being used in other malignancies. These agents, and monoclonal antibodies, form a major component of the ongoing Authority Prescription requirements following the streamlining of a number of agents in 2009. Most Oncologists in fact use a phone authority system, rather than the post, as the post service is slow and often results in an increased administrative load because of the requirement to re-submit various prescriptions.

2. The disparity between private and public streamlining provisions. It is clear from looking at the attached lists that there is an ongoing, unexplained disparity between the public and private sectors. It is the understanding of PCPA that this disparity dates to previous Federal-State agreements around pharmacy. This appears to provide a clear disadvantage to private medical practice in a setting where protocols are standard across both sectors and where treatments are generally consistent. There is little evidence of any difference in practise between public and private sectors in oncology and similar clarity around the indications for treatment. It also provides confusion for staff working between public and private sectors and it would represent a significant improvement in the present situation if the private hospital sector was treated similarly to the public sector.

3. Complex Authority Prescriptions - Increasingly with high cost drugs there is an increased reliance on Complex Authority approvals. These require considerable clinical information and represent an increasing time burden on clinicians. Indeed, clinicians in particular areas where these drugs are used regularly feel that the time burden imposed by these has come to the point where it has cancelled out the benefits gained in 2009. The turnaround time for Complex Authority Prescriptions now reaches beyond two weeks in many cases. This has a clinical implication where patients are waiting anxiously for treatment in settings where delays may be critical. We have recently highlighted to the PBAC the example of Bortezomib in patients with renal failure in myeloma who require urgent treatment within 24 hours to reduce the risk of dialysis dependent renal failure yet we have no mechanism to prescribe this drug beyond the use of the post. This seems incongruent in the modern electronic age where email, web based systems and even fax are widely available and immensely more efficient.

There also has been an increased reporting of forms being sent back for minor administrative inconsistencies, further delaying the ability for a patient to start a drug which is clearly clinically indicated. In drugs in routine clinical practice such as tyrosine kinase inhibitors in chronic myeloid leukemia and multi kinase inhibitors in renal cell carcinoma reliance on Australia Post seems unjustifiably antique and inefficient. The addition of the new agent pazopanib in sarcoma to the list of drugs requiring ‘Australia Post ‘ approval when the indications are clearly defined is a worrying trend against the Governments stated aim of reducing red tape in this area. The PCPA would be very happy to engage with the PBAC around specific areas where this system could be improved yet still enable the provision of important clinical information. Indeed the electronic systems now being implementing in the UK, as discussed below, would make our systems redundant and provide a wider ability to provide required entrance and outcome data.

4. E-prescribing - In initial discussions around the reform of chemotherapy provision, there was general agreement in direct discussions with The Minister for Health, that the introduction of electronic prescribing and claiming is an essential change to increase efficiency and accuracy. Despite this agreement in 2009, there has been little progress, particularly in the private sector in this area. The PCPA and MOGA have engaged with the Department of Health and Ageing, but this

has change not been regarded as a priority. We are pleased to see the recent commitment by the Minister for Health to progress in this area. We note that there has been extensive experience within the public sector and a long trial at the Epworth Hospital in Melbourne. These trials have not found increased inappropriate use of medications and have provided significant work-flow improvements for physicians and pharmacies. Given the complexities of modern chemotherapy, such systems have been introduced widely internationally and have been regarded as providing significant benefit in terms of safety and financial efficiency . It is important to recognise that these changes have occurred successfully in Europe and North America and are proceeding to an advanced degree, while the Australian system has changed little. We particularly note the development of a chemotherapy prescribing system across the NHS in the United Kingdom that provides not only consistency in the use of protocols, but which provides the ability to nationally collate information regarding chemotherapy usage patterns and broad outcomes. This has been used in the United Kingdom to provide information to guide the costing of new agents and to monitor the effectiveness against the effectiveness seen in initial clinical trials. This is seen in many jurisdictions as an essential component of the rational funding of new drugs. It provides the opportunity to withdraw funding for drugs which either are not found to be effective or for which newer and better agents become available.

In summary, we believe that the present Authority Prescription system is time consuming, unnecessarily complex and is not informed by any clear evidence of benefit to the Australian tax payer and the Australian patient. It is time to reform this system. There have been adequate trials of streamlining and electronic claiming in the public and to a lesser extent, the private sector, without there being evidence of increased and inappropriate use. Australia increasingly lags behind other western jurisdictions in its failure to adapt to technology changes in this area. This is an important opportunity to review the appropriateness of Authority Prescriptions before indeed they are made more complex and less efficient as evidenced by the use of postal submissions for complex agents. We, in the PCPA, are committed to continuing to work with government and the Department of Health to reform this system as initially proposed in 2008. We believe that the outcomes we seek are achievable and will provide ongoing savings to ensure the sustainability of this system. It would also provide the opportunity to introduce new agents and if the progress made in the United Kingdom is considered, it also provides the opportunity to remove on a regular basis, old or ineffective agents to make way for the new.

Yours sincerely

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Private Non-Streamlined Authorities

Antineoplastics and Immunomodulating agents	Private Hospital Authority Required (phone)	Private Hospital Authority Required (Streamlined) Recommended	Public Hospital Authority Required (Streamlined)	Complex Authority Required
ABIRATERONE ACETATE	√	*		
ARSENIC	√	*	√	
AZACITIDINE	√ Phone for continuing treatment only		√ Phone for continuing treatment only	√ Initial prescription
BEVACIZUMAB	√	*	√	
BORTEZOMIB				√
CABAZITAXEL	√	*	√	
CAPECITABINE	√	*		
CETUXIMAB	√	*	√	
DABRAFENIB	√	*		
DASATINIB		*		√
DOXORUBICIN (LIPOSOMAL)	√	*	√	
ERLOTINIB (NSCLC EGFR mutation positive patients)	√	*		
ERLOTINIB (NSCLC EGFR wild-type, after failure of chemotherapy)		*		√
EVEROLIMUS	√	*	√ (transplant indication only)	
GEFITINIB	√	*		
IMATINIB MESYLATE (CML/ALL)	√ Second and subsequent continuing prescriptions only			√ Initial and first continuing prescription
IMATINIB MESYLATE (GIST)	√ Continuing treatment prescriptions only			√ Initial prescription only
INTEFERON-alpha	√	*	√	
IPILIMUMAB	√	*	√	
LAPATINIB DITOSYLATE MONOHYD		*		√
LENALIDOMIDE (myelodysplasia)	√ Second and subsequent continuing prescriptions only	*		√ Initial prescription and first continuing
LENALIDOMIDE (myeloma)	√ Continuing treatment prescriptions only	*		√ Initial prescription
NILOTINIB HCL MONOHYDRATE				√
PANITUMUMAB	√	*	√	
PAZOPANIB (renal cell carcinoma)	√			
PAZOPANIB (soft tissue sarcoma)	√ Written prescription only for Initial therapy			
PEMETREXED DISODIUM	√	*	√	
RITUXIMAB,	√	*	√	
SUNITINIB (RCC/pNET)	√	*		
SUNITINIB (GIST)	√ Continuing prescriptions	*		√ Initial prescription only
TEMOZOLOMIDE	√	*		
THALIDOMIDE	√	*	√	
TRASTUZUMAB	√ Continuing prescriptions	*		√ Initial prescription only

Private Non-Streamlined Authorities cont.

Supportive Care, Anti-infectives and Blood agents	Private Hospital Authority Required (phone)	Private Hospital Authority Required (Streamlined) Recommended	Public Hospital Authority Required (Streamlined)	Complex Authority Required
ZOLEDRONIC ACID (MONOHYDRATE)	√	*	√	
CEFEPIME (AS HCL)	√	*		
CYCLOSPORIN	√	*	√	
CIPROFLOXACIN	√	*		
DARBEPOETIN ALFA PFS	√	*	√	
ELTROMBOPAG	√ Continuing therapy only			√ Initial prescription only
FILGRASTIM SINGLE-USE	√	*	√	
GANCICLOVIR SODIUM	√	*	√	
LANREOTIDE	√	*	√	
LENOGRASTIM	√	*	√	
NORFLOXACIN	√	*		
OCTREOTIDE (MODIFIED RELEASE)	√	*	√	
PAMIDRONATE DISODIUM (S100)	√	*	√	
PEGFILGRASTIM PFS	√	*	√	
PLERIXAFOR	√	*	√	
POSACONAZOLE	√	*		
TACROLIMUS	√	*	√	
VALACICLOVIR	√	*	√	
VALGANCICLOVIR	√	*	√	
VORICONAZOLE	√	*		