Submission to "Post-market Review of Authority Required PBS Listings"

Thank you for the opportunity to make a submission to this review. I am a busy medical oncologist working in both the private and public sectors in Western Australia, seeking to efficiently and effectively care for patients suffering from cancer. This treatment includes chemotherapy, other anti-cancer treatments, and supportive medications such as pain relief and anti-nausea medications. Across the state, there are only a few medical oncologists and we are required to care for a growing number of patients with increasingly complex medical needs. Cancer is now the biggest killer of Australians, but there are also more cancer survivors and more Australians living with cancer. Any ability to reduce the administrative burden, improve efficiency and allow us to spend more time treating patients effectively and with the care they need would be of significant benefit. Unfortunately, the current process of requesting authority for PBS listed drugs is a significant burden and in some cases seems to be getting worse.

Requesting authority for PBS listed medications can occur by phone or by mail – there is no option to request authority electronically through a secure portal online or through popular electronic record programs, or even by fax. Many prescriptions are needed by patients promptly, and therefore a phone authority is required at the time with the patient waiting in the clinic with me for the authorised prescription. When calling for phone authority, I have found that the time I am on hold just WAITING to speak to a representative can vary from a few seconds, to over 6 minutes. The process of obtaining authorisation can take up to 5 minutes, depending on the number of drugs and the competence/efficiency of the PBS employee I am speaking to. If I have to do this a few times per day, then I am potentially spending up to an hour or more every day waiting for or obtaining phone authority for medications. This is time that I really don't have, but I have no option but to waste this time because of the patient's need for the medication.

There are essentially three kinds of medications that I need to request authority for. Firstly, there are medications that I use to treat patient's cancers, which can include chemotherapy and biological therapies. For many of these drugs, the pharmacists I work with (in both public and private) have devised systems that allow these prescriptions to be mailed for authority. However, for oral chemotherapy agents, which patients need to start within a day of their appointment with me, a phone authority is required. The most common drugs in this category for which I need to obtain phone authority are Temozolomide and Capecitabine, but other drugs include Pazopanib, Abiraterone and Sorafenib – I have never been denied authority when calling for these drugs, as long as the patient meets the criteria outlined on the PBS website. I cannot understand why there is not a streamline code for authorisation for these medications, which would still allow the PBS to collect information about why the prescription is being given and would save me time obtaining authorisation. I would strongly recommend that the PBS acts to give these drugs a streamline authorisation code.

The second group of drugs that I have to seek phone authority for is supportive medications that always require authorisation – these include drugs such as Neulasta (a medication that is given after chemotherapy to prevent patients developing an infection and requiring hospitalisation). For some reason, Neulasta is given a streamline code for public hospitals, but requires a phone authorisation for patients receiving the chemotherapy in private hospitals (even though the Neulasta drug may be administered by the patient at home or at their GP clinic). After spending up to 10 minutes on the phone to obtain the authorisation, I often tell patients not to lose the prescription because they can see that it is probably easier to launch an intercontinental missile strike than it is to obtain authority to prescribe Neulasta. I cannot understand why there is a difference in prescribing requirements between public hospitals and private hospitals. I would strongly recommend that the PBS acts to give all medications that have a streamline code for public hospitals a streamline code for private hospitals as well.

The third group of drugs that I have to seek phone authority for is when I need to seek extended quantities of medications for drugs that would normally not require authority to prescribe. Examples of this include opiate based pain relief, anti-nausea drugs (such as metoclopramide), and anti-diarrhoeal drugs (such as loperamide), and other medications (such as dexamethasone). I can understand the rationale for obtaining authority for increased quantities of pain relief. However, I cannot understand the current restrictions on prescribing greater quantities of metoclopramide, dexamethasone or loperamide. Currently on the PBS and without phone/mail authorisation, I am only able to prescribe 25 tablets of metoclopramide WITHOUT repeats, and yet patients sometimes have to take 4 or more of these tablets every day to control their nausea. Metoclopramide is NOT a high cost drug, and yet if the patient needs more than 25 tablets before their next appointment then I will need to call to request authority for a greater quantity of tablets and/or repeats – usually no reason for the authority is requested by the PBS employee, and I have never been denied a request for the authority, but it takes several minutes to obtain the authority and I cannot see that this is a useful way to spend my time or the time of the PBS employee reading out the authority number. The same problems apply to loperamide and Dexamethasone. I would strongly urge the PBS to consider removing restrictions on the number of tablets and repeats that can be prescribed for these drugs for cancer patients, even if a streamline code is required to do this. Cancer patients often have problems with nausea and/or diarrhoea and we should not be hampered in our ability to effectively treat these symptoms, especially when the treatment is cheap and effective and when the consequences of not treating these symptoms can be significant and even lead to more costly emergency hospitalisation.

Finally, I want to point out the increasingly complex criteria required to meet PBS requirements for the prescription of some cancer drugs. In particular, a drug called Erlotinib. Prior to January 2014, this drug could be obtained with phone authority and answering a few questions (a process that typically only took a few minutes). Prior to January 2014, we were able to prescribe the drug (with authority) on the PBS according to nationally and internationally accepted guidelines for the second or third line treatment of patients with “metastatic non-small cell lung cancer without a known

sesnsitising EGFR mutation". From January 2014, however, changes were made to obtaining PBS authority for prescription of this drug which means that I am no longer able to treat patients according to international guidelines, or even national guidelines sponsored by the Australian Government (http://wiki.cancer.org.au/australia/Guidelines:Lung_cancer). These changes, I believe, were made without consultation, without any clinical evidence to support them, and now the PBS criteria are inconsistent with treatment guidelines. The process to obtain PBS authorisation is now so complex and time-consuming that I sometimes fear I may not bother prescribing this drug in the future even though there would be clinical rationale for prescribing it. I would like to outline the process of obtaining PBS authority for Erlotinib in this setting – I believe that this is the most complex process of any drug on the PBS and yet it is for the treatment of the most common cause of cancer death in Australia and therefore affects a significant number of patients. First, I somehow have to manage to find the new "Initial PBS authority application" form (no easy feat, let me tell you), and print it out. Then I complete the patient's details and my details on the first page. Then the patient and I sign a declaration to confirm our understanding that the patient will only receive Erlotinib for as long as it's controlling the cancer's growth, and of-course these signatures have to be witnessed and signed by a third party who understands that "giving false or misleading information is a serious offence". And then, I progress to the masterpiece that is the second page of this form, which requires 9 checkboxes to be selected out of a possible 15, and incorporate various details of the patient's previous treatment, and then requires me to sign the form (yet again). I then print out and attach the patient's biopsy report to the form. And finally I complete an authority prescription, put all of this paper in an envelope, write the address of the PBS authority department on the front and send it off in the mail to be delivered to Tasmania. In a few days, I'm assured the patient will receive the prescription for his cancer treatment in the mail, and then his local pharmacy will need a couple of more days to get it, and finally the patient can start their treatment. Just to make sure that I get to experience the pleasures of this process repeatedly, I have to complete this paperwork every 4 months for each patient (should they live that long). The changes made to the prescribing authority for this drug are a travesty. I would strongly urge the PBS to revert back to the process that was in place before January 2014, or, at the very least, significantly improve the current process to make it less complex and restrictive. Many of my colleagues believe that the changes to the authorisation of Erlotinib were simply made to save the PBS money by making it too difficult for oncologists to prescribe the drug – I hope that this is not true and hope that the PBS is genuinely interested in allowing patients to receive treatment that has been proven and accepted to be cost effective by the PBS.

In summary, I became a doctor to care for patients to the best of my abilities. And yet, I seem to have to spend a significant part of my day obtaining PBS authorisation for various drugs. In many cases this seems overly complex and unnecessary. These PBS authorisation requirements can and need to be simplified and streamlined, and I urge the PBS to do this as soon as possible.

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