Commonwealth Department of Health Review of the Efficient Funding of Chemotherapy (EFC) program – Interim report

27th October 2022

This submission has been prepared jointly between Cancer Council Australia (Cancer Council), the Clinical Oncology Society of Australia (COSA), the Medical Oncology Group of Australia (MOGA) and the Australasian Leukaemia and Lymphoma Group (ALLG).
Cancer Council is Australia's peak national non-government cancer control organisation and advises the Australian Government and other bodies on evidence-based practices and policies to help prevent, detect and treat cancer.
The Clinical Oncology Society of Australia is the peak national body representing health professionals from all disciplines whose work involves the care of cancer patients.
The Medical Oncology Group of Australia is the national, professional organisation for medical oncologists and the profession in Australia.
The Australasian Leukaemia and Lymphoma Group is a not-for-profit clinical trial organisation that sponsors local and international investigator initiated clinical trials.

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Cancer Council, COSA, MOGA and ALLG appreciate the opportunity to review the Efficient Funding of Chemotherapy (EFC) Review Interim Report and provide feedback to its findings and recommendations. Our organisations represent the experience of patients, cancer pharmacists, and prescribers of chemotherapy, including medical oncologists and specialists working in regional and rural cancer services. We welcome further discussion with the Review Team and Department of Health on this issue.

General comments:

The Interim Report is comprehensive in both the evidence gathered and reported, and its recommendations. The subject matter expertise within the Review Team, and technical skills of the economic evaluation team, completed a considered and thorough review into the Program's efficiency and patient access to specialist cancer medicines. The Department of Health's decision to appoint a Review Team with in-depth insight and subject matter expertise on this topic enabled practical and impactful recommendations, and we encourage the Department to consider continuing the appointment of such specialist review teams as appropriate.

While the scope of the EFC Review means that some of the points raised in our submission relating to service delivery are not reflected within the recommendations, we expect that these issues can be reflected in the proposed supplementary material being prepared by the Review Team documenting other related issues impacting cost and patient access that arose during the review. Although sitting outside the scope of funding cancer medicines under the EFC Program, these issues are critical to patient safety and treatment efficacy, reducing the burden and cost of preparing and administering these medicines placed on services, and provision of equitable access to appropriate treatment in a timely manner.

Given the need for legislative change and the far-reaching nature of the Interim Report's recommendations if they are adopted, positioning the recommendations in the short, medium and long term timepoints, and at a systems level is a sensible approach to achieving sustainable and long-term improvements. This also enables incremental steps to progress towards a cancer medicines funding system which incorporates both the funding of cancer medicines, and funding to support all aspects of cancer medicines delivery with the aim to reduce costs to the patient and the health system, and reduce delays in access, particularly for people living in rural and remote areas.

Comment's related to specific recommendations:

While our organisations support all recommendations in the report, below we have highlighted some recommendations that will directly address concerns raised in our submission to the EFC Review.

- In alignment with our submission, Recommendation 1 to *Modify the EFC legislative instrument to recognise that the program funds more than chemotherapy and intravenous cancer medications,* should therefore fund medicines such as, bone modifying, and endocrine agents given parenterally (administered through methods other than orally) which are not classified as chemotherapy and therefore, are currently not eligible for funding by the EFC program. This may also enable funding for the administration of

systemic anti-cancer therapies by means other than intravenously. For example, Gemcitabine for bladder instillation is not funded under the EFC Program as it is not intravenously administered.

- Recommendation 2, *investigation of alternative funding mechanisms for the delivery of cancer medicine services that better integrate all aspects of the care pathway,* would recognise the importance of other functions and reimburse for them, to support the quality delivery of cancer medicines for all services, regardless of location and whether medicines are prepared on site or by a third party.

  Most reimbursement elements under the current EFC Program are related to the preparation of chemotherapy, therefore rural and remote sites relying on third party suppliers are unable to claim for their services, such as checking the chemotherapy dose is accurate before it is administered to patients (COSA, n.d.).

- Recommendation 3, *to consider the potential for the Commonwealth to purchase medicines directly from manufacturers as a means of increasing system efficiency and more directly align the purchase and reimbursement of PBS medicines*, may have positive implications for several limitations for the existing EFC program outlined in our submission. This relates to the additional costs that are imposed on organisations required to outsource compounding, particularly in rural and remote areas. It would also reduce the disparity between the third-party compounding fee structures and the PBS reimbursement for compounding fees. For example, if a medicine is supplied in three separate containers, such as three syringes, the treatment centre is charged for three compounding fees by the third-party provider however, the EFC Program will only reimburse for a single compounding fee. Similarly, Recommendation 5 and its sub-points, relating to consideration given to *amending the EFC fee components and levels to add specific payments*, may address these concerns.

  Relating to 5 a., *infusion devices (e.g., elastomeric infusers, Cadd devices) required for the administration of the compounded pharmaceutical product*, consideration should be given to the use of innovative technologies such as closed system devices which limit the medicines exposure to outside contaminants and exposure of hazardous cytotoxic anti-cancer treatment to health professionals and patients. This infrastructure has been difficult to implement due to their high costs. Funding towards this would enable consistent safety and quality practices.

  Relating to Recommendation 5 c., *recognition of the activity required for repurposing/reissue of compounded medicines*, our organisations would like to see an in-depth investigation of an appropriate incentive for this activity. In our original submission we reported that a single hospital pharmacy alone saved over $1.5 million dollars from reassigning doses (Appendix A – poster presentation from the COSA Annual Scientific Meeting 2019). This creates savings to the PBS, has positive effects on the environment from not discarding these doses and supports sustainability. Many pharmacies currently do not reassign cancer therapies, especially in private services when there is a financial incentive to not reassign, since it can affect their own revenue.

In our opinion, the pharmacy should be paid the equivalent of a compounding fee at the least to represent the time invested into reassigning each dose. Where the compounder identification is entered into the compounder section of the dispense system, a "reassignment" selection could be made which then triggers for the reassignment reimbursement (and be set up so that no PBS reimbursement is paid, since the dose has already been claimed) (Ryan, King & Cameron, 2019).

- Recommendation 8, *to expand medicines covered under the EFC to include all compounded cancer medicines listed for cancer indications on the PBS*, will support improved equity of access to subsidised medicines, and reduce the administrative burden on prescribers to know what is listed, what is not and understand how to apply for a medicine.

  Further consideration should be given to reducing the impact of separate processes, whether a cancer medicine is funding through the EFC or PBS only, as both ultimately claim through the PBS.

- Recommendation 11, *Government should investigate the requirements and feasibility of establishing a National Centre for Stability Testing to increase the shelf-life of compounded products under conditions that can be replicated by local compounders*, would begin to address concerns around shelf life of some medicines and the current access and cost implications for rural and remote services to maintain a supply of high-cost anti-cancer medicines and related therapies, raised in our submission. Investment in stability testing of an expensive compounded cancer therapy with a short expiry time (e.g., 24 hours) to potentially extend the shelf life to 72 hours or a few days, has greater benefit for cancer services than investing in stability testing to improve an expiry time of a cancer therapy with an already reasonable expiry such as from 60 to 90 days. This will benefit patients access to potential therapies and potential savings to the PBS from reduced waste due to discarding of expired doses.

- Recommendation 17, to *consider the potential for the Commonwealth to purchase medicines directly from manufacturers as a means of increasing system efficiency and reducing pharmacy/hospital exposure to cost pressures associated with purchasing and carrying EFC-listed stock,* may bring long term system change to address concerns related to wastage and efficient use of drugs, and address the lack of transparency as to how funding is allocated on a per vial basis. For example, blinatumomab is included on the EFC Program arrangements as whole dispensing, the process of dispensing the prescription for the entire course of treatment, involving multiple manufacturing events, however, only a single manufacturing fee is paid per prescription. The vial volume for blinatumomab is different between what is listed by the pharmaceutical company and what is listed on the PBS. Existing administrative processes for medicines such as blinatumomab and azacytidine, enables prescription for vials to be ordered to fulfill multiple doses for a single patient, however, if the patient ceases treatment or dies before using all doses the PBS has already paid for more doses than will be used.

  Additionally, Recommendation 14, adopt a per-mg reimbursement model as the most efficient use of cancer medicines, may overcome the exist cap arrangements on

chemotherapy which can delay access for people with obesity and cancer. For example, the maximum amount of rituximab able to be supplied under the PBS is 800mg. Doses greater than 800mg require a telephone call which impacts clinical time for prescribers. This recommendation supports the new guideline recommendations (COSA n.d.) of not capping chemotherapy for people with obesity and cancer.

- Recommendations 18-21 relate to providing equitable access to funded cancer medicines regardless of the setting in which it is prescribed, reducing variation in out-of-pocket costs, access to Closing the Gap payments and Schedule II medicines. These recommendations could also consider changing the EFC Program rules related to the prescribing of Related Benefits items which requires patients to return another day to access these supportive care medicines (Services Australia, 2020) which is contrary to delivery of optimal patient centred evidence-based cancer care.

  Our organisations support the Interim Report's transition arrangements to ensure continued and appropriate access to treatment, encourage innovation and facilitate collaboration in Australia's cancer medicines supply chain. These transitioning components and additional activities and issues that impact on oncology medicines care that fall outside of the EFC, should be the subject of ongoing investigation and consultation beyond the Review. Our organisations would be interested in being consulted as part of Recommendation 21, *conduct a system wide consultation on the provision of cancer services to consider initiatives that may improve access to care.* This will necessitate the combined consultation of State/Territory and Commonwealth Governments, and key health organisations.

- Recommendation 22 and its sub-points relating to Standards should be equitably applied to rural and remote locations, and metropolitan areas. To do so, consideration should be given to providing funding to less resourced services/regions to support achieving standards. This may fall out of scope for this review but should be noted within the proposed supplementary material being prepared by the Review Team documenting other issues impacting cost and patient access.

- *Removing the distinction between (s94) public and private hospital with respect to PBS item codes* (Recommendation 23) and *with respect to the EFC fees paid for the supply of cancer medicines* (Recommendation 24) is an important step to reducing unnecessary administrative burden on prescribers and out-of-pocket costs to patients.

References:

COSA guidelines for the safe prescribing , dispensing and administration of systematic cancer therapy, How is dosage of cancer therapy calculated for adults? , accessed at https://wiki.cancer.org.au/australia/Clinical_question:How_is_dosage_of_cancer_therapy_calculated_for_adults%3F

Ryan, M., King, J.B. & Cameron, C.L. 2019. Parenteral cancer medicines reassignment – should pharmacies be reimbursed for their staff time? A preliminary analysis. Poster presented at the 2019 Clinical Oncology Society of Australia Annual Scientific Meeting. Provided at Appendix 1.

Service Australia 2020. Education guide- Efficient Funding of Chemotherapy (EFC) Section 100 arrangements. Accessed on 8 July 2021 via https://www.servicesaustralia.gov.au/organisations/health-professionals/topics/education-guide-efficient-funding-chemotherapy-efc-section-100-arrangements/31676#a1

Appendix A

Parenteral cancer medicines reassignment- should pharmacies be reimbursed for their staff time? A preliminary analysis

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Background

The Australian Government spent over $1.5 billion on chemotherapy medicines under the Pharmaceutical Benefits Scheme (PBS) during the 2017-2018 financial year.[1] At the Princess Alexandra Hospital (PAH), most parenteral cancer medicines (PCM) are manufactured in advance due to the time required to manufacture them; however this can lead to wasted doses. Reassigning unused PCM rather than discarding the dose, requires unremunerated pharmacy resources.

Aims

1. To calculate how much money the PAH saves the PBS annually by reassigning unused PCM.
2. To determine the average time it takes a staff member to reassign a dose, and the staff labour cost associated with reassigning a dose.

Method

All PCM reassigned during May 25th 2018 to May 24th 2019 were analysed. Only reassigned doses eligible for PBS reimbursement were included. The total amount saved was calculated by adding together both the PBS claim price and compounding fee for each dose. A time-in-motion study of PCM reassignment was carried out, and the average time taken to reassign a dose was then multiplied by the average hourly rate of pharmacy staff involved in PCM reassignment.

Results

PAH saved the PBS over $1.586 million in the claim price of PCM

PAH saved the PBS $96,620 in compounding fee reimbursement

1581 doses were reassigned

On average, it takes 10 minutes to reassign a dose = $10 staff labour cost per dose

Conclusion

Reimbursement to pharmacies reassigning PCM may provide an incentive to increase reassignment nationally, thereby contributing to the financial sustainability of the PBS. Further investigations into other pharmacy resource considerations (such as cost of storage for unused PCM) will further inform a proposed reimbursement fee. Once the final analysis is complete, the positive environmental impacts[2] of reassigning PCM and the cost saving from the reassigned PCM not requiring incineration, will also be reported on.

1. Department of Health. Expenditure and Prescriptions Twelve Months to 30 June 2018. Canberra: Australian Government; 2018. Available from: https://www.pbs.gov.au/statistics/expenditure-prescriptions/2017-2018/expenditure-and-prescriptions-twelve-months-to-30-june-2018.pdf [cited 21 May 2019]
2. Sharma R, Sharma M, Sharma R, Sharma V. The impact of incinerators on human health and environment. Reviews on Environmental Health. 2013; 28(1): 67-72

We care about you

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