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Sustainable funding model for the provision of chemotherapy to patients in private hospitals

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Contact for further information
Helen Dowling, CEO
The Society of Hospital Pharmacists of Australia
Email: shpa@shpa.org.au

Executive Summary

Contemporary cancer treatment demands complex protocols of multiple chemotherapy medicines administered both sequentially and in parallel, together with standard support therapies. All of these medicines must be used and considered along with the patients 'usual' medicines for their pre-existing medical conditions.

SHPA believes that the current dilemma is driven by the inability of the PBS system, based on a retail model, to cope with the complexity and demands of contemporary cancer services.

For this reason, SHPA supports a revised and transparent model that clearly identifies the four component costs:

1. the **cost of the chemotherapy medicine** (payable for each medicine prepared) and the cost of all support medicines available through the PBS
2. the **cost of consumables/devices** (if any) used in the preparation of each medicine and, if required by the chemotherapy protocol, the cost of the delivery device (payable for each medicine prepared)
3. a **preparation and reconstitution fee** (payable for each medicine prepared)
4. a **pharmacy professional services fee**(s) covering the
    - pre-treatment interview with the patient and pre-treatment clinical pharmacy review undertaken with other healthcare professionals involved in the patient's care (payable per course of chemotherapy)
    - clinical pharmacy review of each cycle of chemotherapy undertaken with other healthcare professionals involved in the patient's care (payable for each cycle of chemotherapy in the prescribed course of treatment).

SHPA believes that a 'ready-made' option for the funding of professional pharmacy services could be achieved through a review of the business rules for the funding of professional pharmacy services through the 5CPA. An additional category **Chemo MedsCheck** (with the same or similar definition as the Diabetes MedsCheck) could be added to the MedsCheck group of professional pharmacy services; along with the appropriate fee structure that takes account of the greater complexity, and / or time involvement in the initial pre-treatment interview structure (i.e. a $90 flat fee or a tiered approach consistent with MBS claimable items).

This approach would require amendments to the eligibility criteria, definitions and business rules relating to services funded through the 5CPA, specifically it would require that:

- Section 94 private hospital pharmacy services (as well as Section 90 private hospital pharmacy services) are eligible to claim for these services; and
- Multiple Chemo MedsChecks can be claimed for individual consumers in the same year.

A second option would require the creation of a new range of claimable items for pharmacist services within the MBS. The description of **MBS items for clinical pharmacy services** would support equity of access across the country and allow all consumers to access clinical pharmacy services when they receive chemotherapy irrespective of the ownership of the pharmacy. As the pharmacist providing the service would charge for the service this approach would be equally applicable across all hospitals / types of pharmacy services.

This approach would require amendments to the eligibility criteria, definitions and business rules relating to MBS items, specifically it would require that:

- all registered pharmacists are eligible to claim for these services and
- pharmacists could claim multiple MBS items for individual consumers in the same year.

Either option would support equity of access across the country, offer a more transparent funding model, and allow all consumers to access clinical pharmacy services when they receive chemotherapy irrespective of the ownership of the pharmacy.

Background

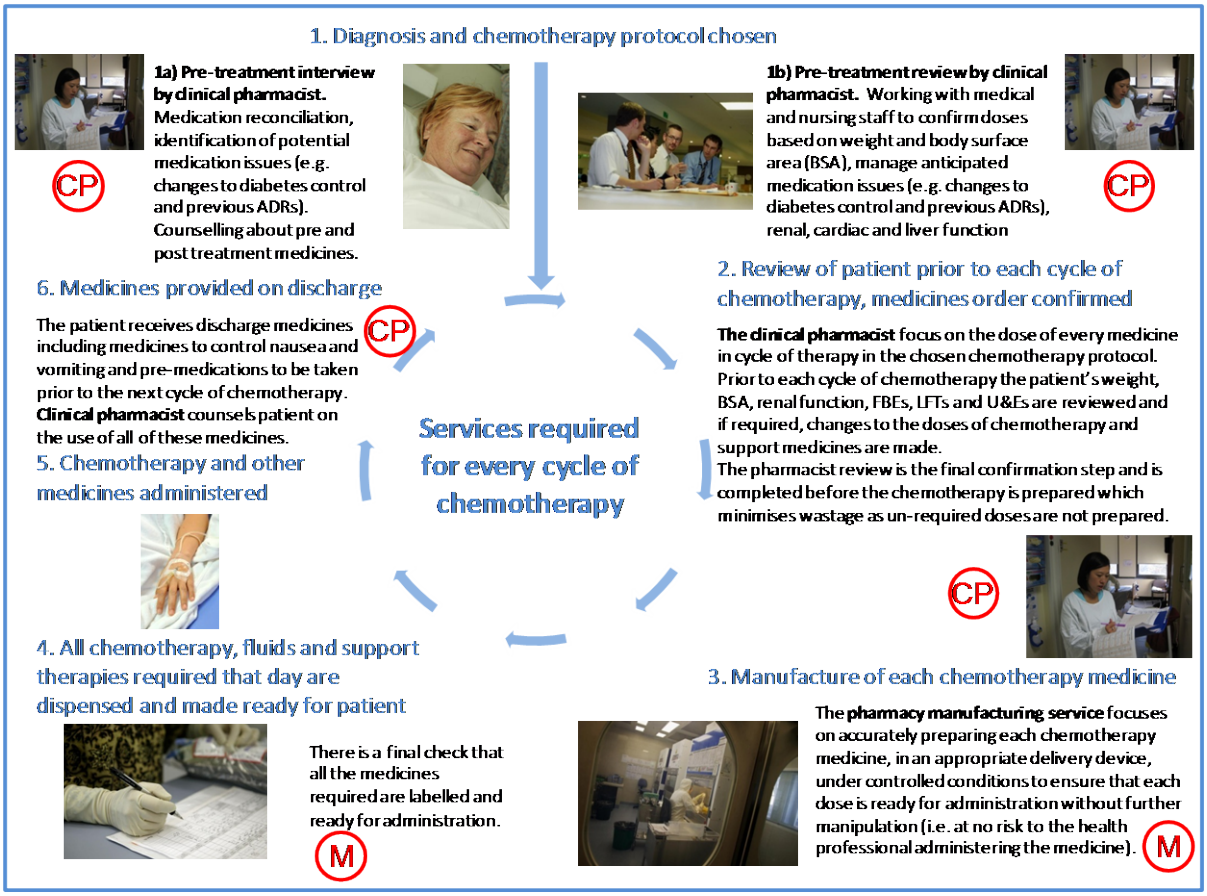
The Society of Hospital Pharmacists of Australia (SHPA) is the national professional organisation for over 3,000 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system. SHPA is the only professional pharmacy organisation with a core base of members practising in public and private hospitals and other health service facilities.

On 1st December 2012, a (revised) 76.2% decrease in the reimbursement for docetaxel was put into effect resulting in a 'perfect storm' between the Expanded and Accelerated Price Disclosure arrangements for PBS medicines and the Efficient Funding of Chemotherapy Drugs initiative (EFC).

Pharmacies and private hospitals have been reliant on the trading terms of medicines, like docetaxel, to cross subsidise other medicines and other pharmacy services such as clinical pharmacy services for many years.

The figure below details the steps required for chemotherapy medicines to be administered to each patient. The symbol (CP) shows the clinical pharmacy services that have, until December 2012, been funded through the difference between the reimbursement and purchase price. The symbol (M) shows the two manufacturing steps which are partially or fully covered through the combination of the current ready-prepared dispensing fee, reconstitution / preparation fee, diluents fee and distribution fee.

The costs associated with installing and maintaining the clean room infrastructure required to manufacture chemotherapy medicines (analogous to theatre facilities) have also been funded through the difference between the reimbursement and purchase price.



SHPA believes that the current funding dilemma is driven by the **inability of the PBS system, designed mid last century (i.e. based on a retail model), to cope with the demands of contemporary cancer services.** Contemporary cancer services delivered via both public and private systems and into rural and regional Australia, require a clinical services based funding model.

Contemporary cancer treatment demands complex protocols of multiple chemotherapy medicines administered both sequentially and in parallel, together with standard support therapies (e.g. anti-emetics to ameliorate side effects such as nausea), and specific electrolyte replacements and hydration fluids. All of these medicines must be used and considered along with the patients 'usual' medicines for their pre-existing medical conditions.

Pharmacists have a key role in managing the risks associated with the use of chemotherapy medicines. **Every dose of every chemotherapy medicine for every individual patient must be:**

- **calculated within the protocol being used**
- **confirmed as appropriate for that patient on that day considering their clinical parameters and use of other medicines**
- **supported with the use of appropriate anti-emetics, electrolyte replacement, hydration fluids etc.**
- **prepared for administration to minimise the risk to both the patient and the health professional administering the chemotherapy medicine.**

Pharmacists have three key roles in the safe delivery of chemotherapy medicines; the current funding model linked to the supply of medicines only covers the cost of pharmacist counselling for supplying medicines and partially covers the cost of preparing chemotherapy medicines. In addition, as medicines are accessed through the PBS this limits the pharmacy's / hospital's ability to recoup the cost from either the patient or private health insurer.

Clinical pharmacy services:

- **for the individual patient** focus on confirming the appropriate dose of every medicine (modified for weight, body surface area (BSA), renal or liver function and blood chemistry) in every cycle of therapy in the intended chemotherapy protocol: the calculated dose of every chemotherapy medicine including the cumulative or acute toxicity the patient has experienced, the mode of delivery, the appropriate fluid for delivery, and appropriate support therapies such as anti-emetics, electrolyte replacement etc. This pharmacist review is the final confirmation step and is completed before the chemotherapy is prepared which minimises wastage. (If treatment needs to be deferred, pre-prepared doses are wasted.)
- including **system-wide strategies** that involve medication safety pharmacists and pharmacy managers working to prevent errors (e.g. ensuring appropriate prescribing protocols, electronic prescribing with decision support, checking procedures, policies for safe handling and transport of chemotherapy medicines, clean room facilities and containment preparation areas).

Pharmacy manufacturing services:

- that focus on the accurate reconstitution and preparation for each chemotherapy medicine, in an appropriate delivery device, under controlled conditions to ensure that each dose is ready for administration without further manipulation (i.e. at no risk to the health professional administering the medicine).

Identifying a transparent and fair structure for the funding of chemotherapy medicines

SHPA proposes a transparent and fair funding model for the provision of chemotherapy medicines that:

- supports equity of access across the country and is equally applicable across **all hospitals / types of pharmacy services** and whether or not an external compounder is used
- covers in full the cost of the medicine or medicines
- provides for the range of costs associated with the reconstitution and preparation of the medicine or medicines in a ready-to-use form
- recognises and allows for payment of the clinical pharmacy services that support the safe use of these toxic medicines.

SHPA is committed to assist government to solve this matter by identifying a more appropriate and transparent funding mechanism based on the components of care (i.e. recognising and including the clinical service component).

A key issue to be addressed is that the current funding system discriminates between patients because of the ownership of the pharmacy; this is incompatible with contemporary cancer care and community expectations.

Ideally the funding model should:

- provide transparency for government, hospitals, insurers and pharmacists and consumers
- remove the need for payment cross subsidisation (which currently underpins the system) and
- address the obvious shortfall in several of the current remuneration categories which are based on the assumption that the service is only the purchase of a product.

The funding model needs to acknowledge the complexity of providing treatment with chemotherapy; in particular:

- the wide range of protocols used (with considerable variation in the number of cycles of chemotherapy) and the number of days of treatment / number of chemotherapy medicines administered in each cycle of treatment and
- the clinical review process that occurs prior to a course of chemotherapy being prescribed and the clinical review process that is required prior to and during each cycle of chemotherapy in the prescribed course.

For this reason, SHPA supports a model that has four component costs:

1. the cost of the chemotherapy medicine (**payable for each medicine prepared**) and the cost of all support medicines available through the PBS
2. the cost of consumables/devices used in the preparation of each medicine and, if required by the chemotherapy protocol, the cost of the delivery device (**payable for each medicine prepared**)
3. a preparation and reconstitution fee (**payable for each medicine prepared**)
4. a pharmacy professional services fee(s) covering the

- pre-treatment interview with the patient and pre-treatment clinical pharmacy review undertaken with other healthcare professionals involved in the patient's care (**payable per course of chemotherapy**)
- clinical pharmacy review of each cycle of chemotherapy undertaken with other healthcare professionals involved in the patient's care (**payable per cycle of chemotherapy**).

Each course of chemotherapy consists of multiple cycles of chemotherapy medicines given according to a pre-defined protocol (adjusted on the basis of specific-patient parameters). Each course of chemotherapy will have a specific treatment goal (e.g. adjuvant, neo-adjuvant, curative, palliative) which will dictate which protocol is used and when chemotherapy treatment should cease.

To explore how this type of model would be applied SHPA provides two different chemotherapy protocols as examples (see Appendix 1).

The first example shows a 'relatively simple' course of chemotherapy for breast cancer: two chemotherapy medicines (and support medicines) given over three hours each day, 21 days apart for four cycles. In this instance one cycle of the chemotherapy is delayed as the patient is too unwell.

In this example the funding of four chemotherapy cycles administered over a 71 day period would consist of:

- 4 x the cost of the chemotherapy medicines docetaxel and cyclophosphamide
- 8 x the cost of consumables/devices used in the preparation of each chemotherapy medicine (if any are required to administer the medicine)
- 8 x a preparation and reconstitution fee
- 6 x pharmacy professional services fees (1 x pre-treatment interview with the patient and pre-treatment clinical pharmacy review undertaken with other healthcare professionals involved in the patient's care and 5 x clinical pharmacy review of each cycle of chemotherapy)

The second example shows a more complex course of chemotherapy for diffuse large B-cell lymphoma. This treatment protocol consists of six cycles of chemotherapy (3 chemotherapy medicines and 21 support medicines) given over three days, administered 28 days apart.

In this example the funding of the six chemotherapy cycles administered over 18 days in a 133 day period would consist of:

- 6 x the cost of the chemotherapy medicines rituximab, fludarabine and cyclophosphamide (42 doses in total)
- 42 x the cost of consumables/devices used in the preparation of each chemotherapy medicine (if any are required to administer the medicine)
- 42 x preparation and reconstitution fee
- 7 x pharmacy professional services fees (1 x pre-treatment interview with the patient and pre-treatment clinical pharmacy review undertaken with other healthcare professionals involved in the patient's care and 6 x clinical pharmacy review of each cycle of chemotherapy)

Although these examples differ in protocol, complexity, side effects, and duration the proposed model is equally applicable.

Identifying a transparent and fair system for the funding of chemotherapy medicines and chemotherapy services

As noted earlier it is crucial that the remuneration system developed supports equity of access across the country and is equally applicable across all hospitals / types of pharmacy services and whether or not an external compounder is used.

Maintaining a funding system that discriminates between patients because of the ownership of the pharmacy is incompatible with contemporary cancer care and community expectations.

Any solution proposed must be equally applicable to and accessible by all private hospital pharmacies as the range of pharmacy services required by cancer patients and the costs of these services do not greatly differ between private hospitals.

Government funding should not be contingent upon the ownership of the pharmacy service, membership to a specific professional organisation, or the profit / not-for-profit status of the pharmacy service as it is currently. It should be contingent upon services required by individual patients, patient eligibility and the services actually delivered by the pharmacy service.

Funding of the reconstitution and preparation of chemotherapy

SHPA believes that the structure of the current remuneration system for the reconstitution and preparation of chemotherapy medicines is based on how medicines were prepared in community pharmacies in the 1940s i.e. a retail purchasing / funding model.

The funding for chemotherapy services should be reviewed to reflect how chemotherapy medicines are prepared under sterile conditions in dedicated clean rooms in accordance with national standards. http://www.shpa.org.au/lib/pdf/practice_standards/cyto_drugs_ro.pdf

The current remuneration system comprises of:

- a distribution fee of $24.38 (previously based on the cost of the medicine) which is designed to cover the cost of accessing the medicine from the supplier i.e. covers the ‘business cost’ of purchasing and storing these expensive medicines in the manufacturer’s packaging
- a ready-prepared dispensing fee of $6.52 that is also applied to other medicines
- a diluent fee of $4.83 which implies that the medicines are only reconstituted and supplied in the original container rather than prepared in a ready-to-use form, which may include the cost of delivery devices required for the dose to be administered
- a preparation fee of $40.64, which is not sufficient to cover the infrastructure and staff costs associated with compiling the consumables and materials required to manufacture each dose of chemotherapy, the manufacture of each medicine (reconstitution, measuring of dose and placing dose into delivery device or infusion solution) and the checking of the dose to ensure the correct dose has been placed in the correct delivery device / infusion solution.

That is, the current fee for the purchasing of the medicine, compiling the consumables and materials required to manufacture each dose of chemotherapy, the manufacture of each medicine (reconstitution, measuring of dose and placing dose into delivery device or infusion solution) and the checking of the dose to ensure the correct dose has been placed in the correct delivery device / infusion solution is $76.37.

SHPA believes that a more equitable and transparent model for **the reconstitution and preparation of chemotherapy** would have three component costs for each medicine prepared:

1. the cost of the chemotherapy medicine in line with the 'usual' remuneration structure through the PBS
2. the cost of consumables / devices used in the preparation of each medicine and, if required by the chemotherapy protocol, the cost of the delivery device. This structure component could be based on / added to the extemporaneously prepared pharmaceutical benefits
3. a chemotherapy reconstitution and preparation fee set at a rate that reflects the infrastructure and staff costs associated with:
    - purchasing and having available all chemotherapy medicines that may be required by an individual patient
    - compiling the consumables and materials required to manufacture each dose of chemotherapy, the manufacture of each medicine (reconstitution, measuring of dose and placing dose into delivery device or infusion solution) and the checking of the dose to ensure the correct dose has been placed in the correct delivery device / infusion solution
    - ensuring appropriate prescribing protocols, electronic prescribing with decision support, checking procedures, policies for safe handling and transport of chemotherapy medicines, clean room facilities and containment preparation areas are used / supported in the hospital.

SHPA is aware that private hospitals have provided an estimated total payment value required to cover the cost of this third component which we support in principle. Importantly this payment would be required irrespective of where the chemotherapy was prepared, i.e. by an on-site pharmacy service or through an external compounding facility.

Funding of professional pharmacy services

SHPA notes that the current 5CPA already includes payments for professional pharmacy services (MedsCheck) similar to those required by patients receiving chemotherapy. However we understand that the definitions and business rules governing these payments, in their current format, would not be accessible for hospital pharmacies providing professional services to chemotherapy patients and they specifically exclude pharmacy services provided by Section 94 hospital pharmacies.

SHPA believes that this is potentially a 'ready-made' option for the funding of professional pharmacy services which could be achieved through a review of the business rules for the funding of professional pharmacy services through the 5CPA. A second option would require the creation of a new range of claimable items for pharmacist services within the MBS.

Option 1: Definitions and business rules relating to MedsCheck pharmacy services funded through the 5CPA are adjusted to allow services for chemotherapy patients to be funded.

SHPA has relied on the details given in the *Program Specific Guidelines, MedsCheck and Diabetes MedsCheck* published by the Pharmacy Guild and DoHA to formulate this option. (http://www.5cpa.com.au/iwov-resources/documents/5CPA/Initiatives/Medication_Management/MedsCheck_and_Diabetes_MedsCheck/00266%20MedsCheck%20Program%20Specific%20Guidelines%20v.2.pdf)

SHPA believes that a category **Chemo MedsCheck** could be added to the MedsCheck group of professional pharmacy services. SHPA believes that a fee of around $90 per Chemo MedsCheck (i.e. the same as Diabetes MedsCheck) may be appropriate. SHPA notes that a budget already exists for MedsCheck pharmacy services. (However, given that the professional pharmacy service may involve greater complexity, and / or time involvement in the initial pre-treatment interview, it may be appropriate to incorporate a tiered approach to payment which reflects that outlined for new MBS claimable items in Option 2.)

The purpose of a Chemo MedsCheck would parallel that of MedsCheck or Diabetes MedsCheck. "The service includes a review of a consumer's medicines, focusing on education and self-management and aims to:

- identify problems that the consumer may be experiencing with their medicines;
- help the consumer learn more about their medicines including how medicines affect medical conditions;
- improve the effective use of medicines by consumers; and
- educate consumers about how to best use and store their medicines."

The Chemo MedsCheck service would have the same aims with a focus on optimising the use of medicines required as part of chemotherapy treatment and minimising the anticipated / possible side effects of chemotherapy medicines.

The service elements required would be equally applicable to Chemo MedsCheck, they are: "A MedsCheck and Diabetes MedsCheck service involve identifying consumers who may benefit from these services and confirming their eligibility. A consultation appointment is then made with the consumer, providing the consumer consents to receive the service. The Service Elements in conducting a MedsCheck or Diabetes MedsCheck can be summarised as:

a. gathering relevant information from the consumer or consumer's carer;
b. reviewing and discussing the consumer's use of all medicines and medication/monitoring devices;
c. developing a written Action Plan including agreed consumer goals which may include any agreed follow-up with the consumer's GP and/or other healthcare provider(s);
d. providing the consumer with a copy of the Consumer Report which includes the Medicines List and Action Plan;
e. arranging agreed follow-up actions; and
f. claiming payment for the MedsCheck or Diabetes MedsCheck service using the approved Department of Human Services (Medicare) claim form."

Appendix 2 details proposed purpose, service elements and business rules for Chemo MedsCheck.

Chemo MedsCheck would be payable **once per course of chemotherapy** if the service is delivered prior to treatment commencing (to cover the cost of the pre-treatment interview with the patient) and **once per cycle of chemotherapy** where the pharmacist reviews the patient's clinical parameters (i.e. weight, BSA, renal function, cardiac function, FBEs, LFTs and U&Es) and if required, changes to the doses of chemotherapy and support medicines are made and the pharmacist counsels the patient on any changes to their treatment, in particular medicines to control the side effects of the chemotherapy.

That is the pharmacist / pharmacy could only claim for a Chemo MedsCheck service **when a patient interview has occurred, a written action plan is produced and shared with other**

members of the care team and the patient receives an updated medication list and the medication action plan.

It would be inappropriate to maintain the once per year service rule; Chemo MedsCheck would need to be payable once per course of chemotherapy and once per cycle of chemotherapy.

SHPA believes the description of Chemo MedsCheck with a payment per service offers a straightforward, relatively simple solution to the issue of funding clinical pharmacy services for patients receiving chemotherapy.

Budget availability would need to be confirmed for both of these services as well as processes described for confirming eligibility and claiming (although these would need to be amended).

This approach would require amendments to the eligibility criteria, definitions and business rules relating to services funded through the 5CPA, specifically it would require that:

- the pharmacist managers of section 94 private hospital pharmacy services (as well as Section 90 private hospital pharmacy services) are eligible to claim for these services and

- the pharmacist could claim multiple Chemo MedsChecks for individual consumers in the same year.

Option 2: Creation of a new range of claimable items for pharmacist services

This option would involve the description of clinical pharmacy services in the Medicare Benefits Schedule (MBS).

The creation of MBS item numbers for clinical pharmacy services would require that:

- relevant MBS items would need to be described and fees set
- all pharmacists would need to be eligible to make claims through the MBS and
- a budget defined within the MBS for clinical pharmacy services.

As with other MBS items the potential for 'out of pocket' expenses will remain. The pharmacist provider can charge any rate with consumer benefit equal to the MBS fee.

Many registered allied health professionals already have services described under *Individual Allied Health Services (Items 10950 to 10970) for Chronic Disease Management* (e.g. audiologists, dieticians, occupational therapists, physiotherapists, podiatrists, psychologist and speech pathologists) with a fee / benefit of $62.25.

The MBS includes the concept of health assessments where medical practitioners can claim for services based on complexity and time spent with the consumer. MBS Health Assessment items provide a template for clinical pharmacy services in this context.
Conceptually SHPA believes that *Item 707* (prolonged health assessment lasting at least 60 minutes with benefit of $263.55) would be equivalent to the clinical pharmacist pre-treatment interview with the patient and pre-treatment clinical pharmacy review undertaken with other healthcare professionals involved in the patient's care.

Similarly, *Item 701* (brief health assessment lasting not more than 30 minutes with benefit $58.20) *or 703* (standard health assessment lasting more than 30 minutes with benefit $135.20)

would be equivalent to the clinical pharmacist clinical pharmacy review of each cycle of chemotherapy undertaken with other healthcare professionals involved in the patient's care.

SHPA believes the description of MBS items for clinical pharmacy services would support equity of access across the country and allow all consumers to access clinical pharmacy services when they receive chemotherapy irrespective of the ownership of the pharmacy. As the pharmacist providing the service would charge for the service this approach would be equally applicable across all hospitals / types of pharmacy services.

The definition of three MBS items based on complexity of service and the time it takes to provide the service provides a relatively simple solution to the issue of funding clinical pharmacy services for patients receiving chemotherapy.

This approach would require amendments to the eligibility criteria, definitions and business rules relating to MBS items, specifically it would require that:

- all registered pharmacists are eligible to claim for these services and

- pharmacists could claim multiple MBS items for individual consumers in the same year.

Appendix 1

Example 1: a course of chemotherapy for breast cancer

This treatment protocol consists of one course of four cycles of chemotherapy given 21 days apart. Each cycle of chemotherapy takes 3 hours to administer and consists of:

- pre-treatment hydration fluids to minimise renal toxicity associated with cyclophosphamide administered over the hour prior to the docetaxel being administered
- pre-treatment granisetron and dexamethasone for nausea
- docetaxel 75 mg/m^2 given as an infusion in 250 mL over 60 minutes
- cyclophosphamide 600 mg/m^2 given as infusion in 500 mL over 30 minutes, administered after docetaxel
- if required, intravenous hydrocortisone and promethazine for hypersensitivity reactions during or after infusion of docetaxel or cyclophosphamide
- post-discharge dexamethasone and metoclopramide for nausea, patient needs to drink 2 to 3 litres of fluid over the rest of the day after the infusions

Each patient must be reviewed prior to each cycle of chemotherapy with particular attention to cumulative and acute toxicities associated with these two chemotherapy medicines:

- nausea, vomiting and diarrhoea
- renal function
- liver function
- cardiotoxicity
- neurotoxicty
- effects on blood and bleeding
- fatigue, hair loss, skin and mouth problems and fertility

This requires that prior to each cycle of chemotherapy the patient's weight, BSA, renal function, FBEs, LFTs and U&Es are reviewed and if required, changes to the doses of chemotherapy and support medicines are made.

Mrs V has been diagnosed with breast cancer and will receive a course of chemotherapy of four cycles of docetaxel with cyclophosphamide 21 days apart

The treatment protocol for each cycle of chemotherapy comprises of:

- pre-treatment hydration fluids to minimise renal toxicity associated with cyclophosphamide
- pre-treatment granisetron and dexamethasone for nausea
- docetaxel 75 mg/m2 given as an infusion over 60 minutes
- cyclophosphamide 600 mg/m2 given as infusion over 30 minutes
- if required intravenous hydrocortisone and promethazine for hypersensitivity reactions
- post-discharge dexamethasone and metoclopramide for nausea

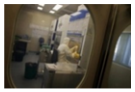
Pre-treatment interview and review (day 1)

Patient interview
Medication reconciliation, identification of potential medication issues (e.g. changes to diabetes control and previous ADRs). Counselling about pre and post treatment medicines.

Pre-treatment review
Working with medical and nursing staff to confirm doses based on weight and BSA, manage anticipated medication issues (e.g. changes to diabetes control and previous ADRs), renal, cardiac and liver function

$ - Clinical pharmacy fee (Chemo MedsCheck)

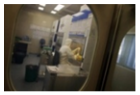
Cycle 1 (day 2)



- Patient parameters checked, doses of chemotherapy are calculated and confirmed. Pre and post treatment confirmed by clinical pharmacist.
- Chemotherapy doses prepared.
- Chemotherapy and other medicines administered
- Discharge medicines and counselling

$ - Price of medicines
Price of consumables
Preparation fee
Clinical pharmacy fee (Chemo MedsCheck)

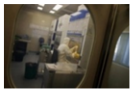
Cycle 2 (day 22)



- Patient parameters checked, doses of chemotherapy are calculated and confirmed. Pre and post treatment confirmed by clinical pharmacist.
- Chemotherapy doses prepared.
- Chemotherapy and other medicines administered
- Discharge medicines and counselling

$ - Price of medicines
Price of consumables
Preparation fee
Clinical pharmacy fee (Chemo MedsCheck)

Cycle 3 (day 43)



- Patient parameters checked, doses of chemotherapy are calculated and confirmed. Pre and post treatment confirmed by clinical pharmacist.
- Chemotherapy doses prepared.
- Chemotherapy and other medicines administered
- Discharge medicines and counselling

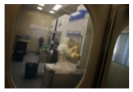
$ - Price of medicines
Price of consumables
Preparation fee
Clinical pharmacy fee (Chemo MedsCheck)

Cycle 4 (day 64)

- Patient parameters checked - Mrs V white cell count is low, treatment deferred for one week

Clinical pharmacy fee (Chemo MedsCheck)
$ - if chemotherapy prepared by onsite pharmacy – nil
$ - If chemotherapy pre-ordered from external compounding facility - Price of medicines
Price of consumables
Preparation fee

Cycle 4 (day 71)



- Patient parameters checked, doses of chemotherapy are calculated and confirmed. Pre and post treatment confirmed by clinical pharmacist.
- Chemotherapy doses prepared.
- Chemotherapy and other medicines administered
- Discharge medicines and counselling

$ - Price of medicines
Price of consumables
Preparation fee
Clinical pharmacy fee (Chemo MedsCheck)

Prior to being diagnosed with breast cancer Mrs V was already being treated for Type 2 diabetes and raised cholesterol. Her renal function is also being closely monitored due to her poor blood glucose control when initially diagnosed with Type 2 diabetes. Therefore, the chemotherapy protocol she will require close monitoring of her blood glucose levels which may lead to changes to her usual medicines (which will be impacted by the use of dexamethasone and possibility of vomiting, dehydration and infection) and her renal function which may be impacted by the use of cyclophosphamide.

After the third cycle of chemotherapy Mrs V records a low white cell count and it is decided that the fourth cycle of chemotherapy should be delayed by one week to allow her white cell count to recover.

In this example the funding for Mrs V course of chemotherapy, administered over a 71-day period would consist of:

- the cost of the chemotherapy medicines docetaxel and cyclophosphamide (payable for each time both medicines are prepared i.e. four times for each medicine if the chemotherapy is prepared by the on-site pharmacy or five times if the doses are pre-prepared by external compounding facility) and the cost of all support medicines available through the PBS (payable when each medicine is required)
- the cost of consumables/devices used in the preparation of each medicine and, if required by the chemotherapy protocol, the cost of the delivery device (payable for each time both medicines are prepared i.e. eight times if the chemotherapy is prepared by the on-site pharmacy or ten times if the doses are pre-prepared by external compounding facility)
- a preparation and reconstitution fee (payable for each time both medicines are prepared i.e. eight times if the chemotherapy is prepared by the on-site pharmacy or ten times if the doses are pre-prepared by external compounding facility)
- pharmacy professional services fees covering the
    - pre-treatment interview with the patient and pre-treatment clinical pharmacy review undertaken with other healthcare professionals involved in the patient's care (payable once for this course of chemotherapy)
    - clinical pharmacy review of each cycle of chemotherapy undertaken with other healthcare professionals involved in the patient's care (payable once per cycle of chemotherapy i.e. five times).

Example 2: a course of chemotherapy for Diffuse large B-cell lymphoma

This treatment protocol consists of six cycles of chemotherapy given 28 days apart. The first day of each cycle of chemotherapy takes 6 hours to administer. Each cycle of chemotherapy consists of:

Day 1

- pre-treatment hydration fluids to minimise renal toxicity associated with cyclophosphamide administered over the 30 minutes prior to the rituximab being administered
- pre-treatment paracetamol, loratadine and hydrocortisone for rituximab hypersensitivity
- rituximab 375 mg/m^2 given as an infusion in 500 mL over 90 to 240 minutes
- pre-treatment granisetron for nausea. Further doses of hydrocortisone and promethazine for rituximab hypersensitivity
- fludarabine 25 mg/m^2 in 100 mL over 30 minutes given after the rituximab
- cyclophosphamide 250 mg/m^2 given as infusion in 500 mL over 30 minutes, administered after fludarabine
- post-discharge metoclopramide for nausea, patient needs to drink 2 to 3 litres of fluid over the rest of the day after the infusions
- for next 28 days (i.e. until next cycle of chemotherapy) patient needs to take allopurinol tablets and use a mouthwash to manage side effects and take prophylactic valaciclovir and trimethoprim/sulfamethoxazole tablets daily to reduce the incidence of infections

Day 2

- pre-treatment hydration fluids to minimise renal toxicity associated with cyclophosphamide administered over the 30 minutes prior to the fludarabine being administered
- pre-treatment granisetron for nausea
- fludarabine 25 mg/m^2 in 100 mL over 30 minutes
- cyclophosphamide 250 mg/m^2 given as infusion in 500 mL over 30 minutes, administered after fludarabine
- post-discharge metoclopramide for nausea, patient needs to drink 2 to 3 litres of fluid over the rest of the day after the infusions

Day 3

- pre-treatment hydration fluids to minimise renal toxicity associated with cyclophosphamide administered over the 30 minutes prior to the fludarabine being administered
- pre-treatment granisetron for nausea.
- fludarabine 25 mg/m^2 in 100 mL over 30 minutes
- cyclophosphamide 250 mg/m^2 given as infusion in 500 mL over 30 minutes, administered after fludarabine
- post-discharge granisetron and metoclopramide for nausea, patient needs to drink 2 to 3 litres of fluid over the rest of the day after the infusions

Each patient must be reviewed prior to each cycle of chemotherapy with particular attention to hypersensitivity to rituximab and acute toxicities associated with cyclophosphamide:

- nausea, vomiting and diarrhoea
- renal function
- liver function
- effects on blood and bleeding
- fatigue, hair loss, skin and mouth problems and fertility

This requires that prior to each cycle of chemotherapy the patient's weight, BSA, renal function, FBEs, LFTs and U&Es are reviewed and if required, changes to the doses of chemotherapy and support medicines are made.

The example shown below (overview of the course of chemotherapy and overview of one cycle of chemotherapy) the funding for Mr L course of chemotherapy, administered over a 168-day period, would consist of:

- the cost of the chemotherapy medicines rituximab, fludarabine and cyclophosphamide (payable for each time the medicines are prepared i.e. six times for rituximab and 18 times each for fludarabine and cyclophosphamide and the cost of all support medicines available through the PBS (payable when each medicine is required)
- the cost of consumables/devices used in the preparation of each medicine and, if required by the chemotherapy protocol, the cost of the delivery device (payable for each time the three chemotherapy medicines are prepared i.e. 42 times)
- a preparation and reconstitution fee (payable for each time the three chemotherapy medicines are prepared i.e. 42 times)
- pharmacy professional services fees covering the
    - pre-treatment interview with the patient and pre-treatment clinical pharmacy review undertaken with other healthcare professionals involved in the patient's care (payable once for this course of chemotherapy)
    - clinical pharmacy review of each cycle of chemotherapy undertaken with other healthcare professionals involved in the patient's care (payable once per cycle of chemotherapy i.e. six times).

Mr L has been diagnosed with Diffuse large B-cell lymphoma and will receive a course of chemotherapy of six cycles of FC-R protocol, 28 days apart

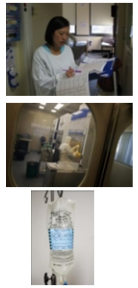
The treatment protocol for each cycle of chemotherapy comprises of:

- pre-treatment hydration fluids to minimise renal toxicity associated with cyclophosphamide
- pre-treatment granisetron for nausea and loratidine, hydrocortisone and promethazine for hypersensitivity
- rituximab 375mg/m2 given as an infusion over 90-240 minutes (day 1 of each cysle)
- cyclophosphamide 250mg/m2 given as infusion over 30 minutes (3 days each cycle)
- fludarabine 25mg/m2 given as infusion over 30 minutes (3 days each cycle)
- if required IV hydrocortisone and promethazine for hypersensitivity reactions
- post-discharge prophylaxis medicines for infections etc

Pre-treatment interview and review (day 1)

Patient interview
Medication reconciliation, identification of potential medication issues
Counselling about pre and post treatment medicines.
Pre-treatment review
Working with medical and nursing staff to confirm doses based on weight and BSA, manage anticipated medication issues and renal function
$ - Clinical pharmacy fee (Chemo MedsCheck)

Cycle 1 (day 2)



- Patient parameters checked, doses of chemotherapy are calculated and confirmed. Pre and post treatment confirmed by clinical pharmacist.
- Chemotherapy doses prepared.
- Chemotherapy and other medicines administered
- Discharge medicines and counselling

$ - Price of medicines & consumables
Preparation fee
Clinical pharmacy fee (Chemo MedsCheck)

Cycle 2 (day 29)

- Patient parameters checked, doses of chemotherapy are calculated and confirmed. Pre and post treatment confirmed by clinical pharmacist.
- Chemotherapy doses prepared.
- Chemotherapy and other medicines administered
- Discharge medicines and counselling

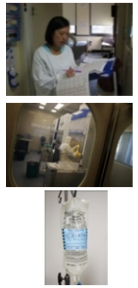
$ - Price of medicines & consumables
Preparation fee
Clinical pharmacy fee (Chemo MedsCheck)

Cycle 3 (day 57)

- Patient parameters checked, doses of chemotherapy are calculated and confirmed. Pre and post treatment confirmed by clinical pharmacist.
- Chemotherapy doses prepared.
- Chemotherapy and other medicines administered
- Discharge medicines and counselling

$ - Price of medicines & consumables
Preparation fee
Clinical pharmacy fee (Chemo MedsCheck)

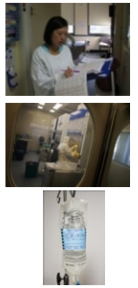
Cycle 4 (day 85)



- Patient parameters checked, doses of chemotherapy are calculated and confirmed. Pre and post treatment confirmed by clinical pharmacist.
- Chemotherapy doses prepared.
- Chemotherapy and other medicines administered
- Discharge medicines and counselling

$ - Price of medicines & consumables
Preparation fee
Clinical pharmacy fee (Chemo MedsCheck)

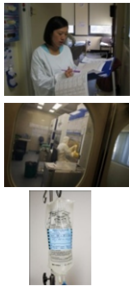
Cycle 5 (day 113)



- Patient parameters checked. **Renal function impaired, dose of fludarabine reduced** pre and post treatment confirmed by clinical pharmacist.
- Chemotherapy doses prepared.
- Chemotherapy and other medicines administered
- Discharge medicines and counselling

$ - Price of medicines & consumables
Preparation fee
Clinical pharmacy fee (Chemo MedsCheck)

Cycle 6 (day 131)



- Patient parameters checked. **Renal function impaired, dose of fludarabine reduced** pre and post treatment confirmed by clinical pharmacist.
- Chemotherapy doses prepared.
- Chemotherapy and other medicines administered
- Discharge medicines and counselling

$ - Price of medicines & consumables
Preparation fee
Clinical pharmacy fee (Chemo MedsCheck)

The treatment protocol for first cycle of chemotherapy for Mr L comprises of:

- pre-treatment hydration fluids to minimise renal toxicity associated with cyclophosphamide
- pre-treatment granisetron for nausea and loratidine, hydrocortisone and promethazine for hypersensitivity
- rituximab 375 mg/m2 given as an infusion over 90-240 minutes (day 1 of each cysle)
- cyclophosphamide 250 mg/m2 given as infusion over 30 minutes (3 days each cycle)
- fludarabine 25 mg/m2 given as infusion over 30 minutes (3 days each cycle)
- if required intravenous hydrocortisone and promethazine for hypersensitivity reactions
- post-discharge prophylaxis medicines for infections etc

Pre-treatment interview and review

Patient interview
Medication reconciliation, identification of potential medication issues Counselling about pre and post treatment medicines.

Pre-treatment review
Working with medical and nursing staff to confirm doses based on weight and BSA, manage anticipated medication issues and renal function

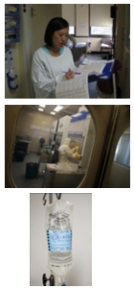
$ - Clinical pharmacy fee (Chemo MedsCheck)

Cycle 1, Day 1

- Patient parameters checked, doses of chemotherapy are calculated and confirmed. Pre and post treatment confirmed by clinical pharmacist.
- Chemotherapy doses prepared.
- Chemotherapy and other medicines administered
- Discharge medicines and counselling

$ - Price of medicines & consumables
Preparation fee
Clinical pharmacy fee (Chemo MedsCheck)

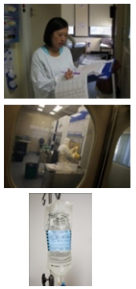
Cycle 1, Day 2



- Patient parameters checked, doses of chemotherapy are calculated and confirmed. Pre and post treatment confirmed by clinical pharmacist.
- Chemotherapy doses prepared.
- Chemotherapy and other medicines administered
- Discharge medicines and counselling

$ - Price of medicines & consumables
Preparation fee

Cycle 1, Day 3



- Patient parameters checked, doses of chemotherapy are calculated and confirmed. Pre and post treatment confirmed by clinical pharmacist.
- Chemotherapy doses prepared.
- Chemotherapy and other medicines administered
- Discharge medicines and counselling

$ - Price of medicines & consumables
Preparation fee

Appendix 2: Proposed business rules for Chemo MedsCheck

A Chemo MedsCheck service would have a focus on optimising the use of medicines required as part of chemotherapy treatment and minimising the anticipated / possible side effects of chemotherapy medicines. The SHPA Standards of Practice for the provision of clinical oncology pharmacy services has been used to formulate the proposed purpose and service elements.
(http://www.shpa.org.au/lib/pdf/practice_standards/ps_clin_onc.pdf)

Purpose

The service includes a review of a consumer's medicines, focusing on optimising the use of medicines required as part of chemotherapy treatment and minimising the anticipated / possible side effects of chemotherapy medicines and providing consumer education and self-management and aims to:

- identify problems that the consumer may be experiencing with their medicines and how their chemotherapy treatment may impact on these medicines;
- help the consumer learn more about their chemotherapy and support medicines including how to use prophylatic medicines to minimise the anticipated side effects of chemotherapy;
- improve the effective use of medicines by consumers; and
- educate consumers about how to best use and store their medicines."

Service elements

A Chemo MedsCheck would require a consultation appointment to be made with the consumer, providing the consumer consents to receive the service. The Service Elements in conducting a Chemo MedsCheck can be summarised as:

a. identification of proposed treatment protocol, treatment goals (e.g. adjuvant, neo-adjuvant, curative, palliative) and therapeutic goals and gathering relevant patient parameters (e.g. body surface area, renal function, weight, blood chemistry);
b. gathering relevant information from the consumer or consumer's carer;
c. reviewing and discussing the consumer's use of all medicines and medication/monitoring devices and assessing outcomes relative to therapeutic goals;
d. predict and recommend ways to prevent potential medicine-related problems and identify and suggest ways to resolve actual medicine-related problems;
e. developing or updating a written Action Plan including agreed monitoring plan and consumer goals in the medical history which may include any agreed follow-up with the consumer's GP and/or other healthcare provider(s);
f. providing the consumer with a copy of the Consumer Report or relevant documentation which includes current Medicines List and Action Plan;
g. arranging agreed follow-up actions; and
h. claiming payment for the Chemo MedsCheck service using the approved Department of Human Services (Medicare) claim form.

Business rules

Consumer eligibility:

- access to Chemo MedsCheck would be independent of access to other MedsCheck service of Home Medicines Review
- consumers would be eligible for multiple Chemo MedsCheck in the same year.

Pharmacist eligibility:

- pharmacists can only claim for a Chemo MedsCheck service when a patient interview has occurred, a written action plan is produced / updated and shared with other members of the care team and the patient receives an updated medication list and action plan.
- Section 90 community pharmaces would claim for Chemo MedsCheck using the same system as other MedsChecks
- individual pharmacists or the pharmacist managers of section 94 private hospital pharmacy services must be able to claim for Chemo MedsCheck
- pharmacists can claim multiple Chemo MedsChecks in the same year, pharmacists can claim a maximum of one Chemo MedsCheck for the assessment prior to chemotherapy commencing and one Chemo MedsCheck per scheduled cycle of chemotherapy
- the service fee could be set at $90 (or at a level or levels that align with a tiered approach to payment and which is consistent with MBS claimable items) per Chemo MedsCheck.