promoting excellence in medicines management

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Submission to Senate Committee:

Supply of chemotherapy drugs such as docetaxel

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About SHPA

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.

SHPA is committed to facilitating the safe and effective use of medicines, which is the core business of pharmacists, especially in hospitals. SHPA supports pharmacists to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved for Australians, as individuals, for the community as a whole and for healthcare facilities within our systems of healthcare.

Key points

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 notes that revenue generated by hospital pharmacy services must cover the cost of providing chemotherapy medicines with an appropriate clinical pharmacy service and infrastructure as well as the cost of doing business with Medicare Australia.

Current business rules do not reflect contemporary cancer services and discriminate between patients based on the ownership of the pharmacy and the hospital where they are treated. SHPA therefore believes the funding for chemotherapy services and administrative processes should be designed to incorporate the following concepts.

1. **A revised and transparent model that clearly identifies the four component costs and is available to Section 90 and Section 94 pharmacies in private hospitals:**

   1.1 the **cost of the chemotherapy medicine** (payable for each medicine prepared) and the cost of all support medicines available through the PBS
   1.2 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)
   1.3 a **preparation and reconstitution fee** (payable for each medicine prepared)
   1.4 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 pharmacist 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).

2. **A revision of the business rules for the claiming of PBS medicines via Medicare Australia.**

   The administrative burden for pharmacists has been entrenched in business rules for re-imbursement since the inception of the PBS. An 'every day' issue across most public and all private hospitals (whether the patient is an inpatient, day patient or being discharged from the hospital) is that revenue generated must cover the cost of doing business with Medicare Australia. There are two business rules regarding the claiming of PBS medicines that substantially contribute to the administrative burden for pharmacists that provide chemotherapy services in private hospitals.

   2.1 Timely access to many chemotherapy medicines is compromised in private hospitals due to onerous authority requirements. These issues had previously been addressed in the public sector through the **Chemotherapy Pharmaceuticals Access program (CPAP), and were carried through into the Efficient Funding of Chemotherapy for public hospitals program. This program should be offered to all private hospital pharmacy providers.**
   2.2 The re-imbursement rules require or presume a 'no script no drug' approach. Doctors must complete and sign two orders for every medicine for a patient to receive that medicine through the PBS from a hospital and for the pharmacy to receive cost reimbursement through Medicare Australia. **All features of the Paperless Claiming Trial (initiated in July 1998 but currently available in only seven private hospitals) should be made available to all pharmacies licensed to supply PBS medicines in private hospitals irrespective of the medicine, type of hospital or care facility or the type of pharmacy service accessed by the patient.**

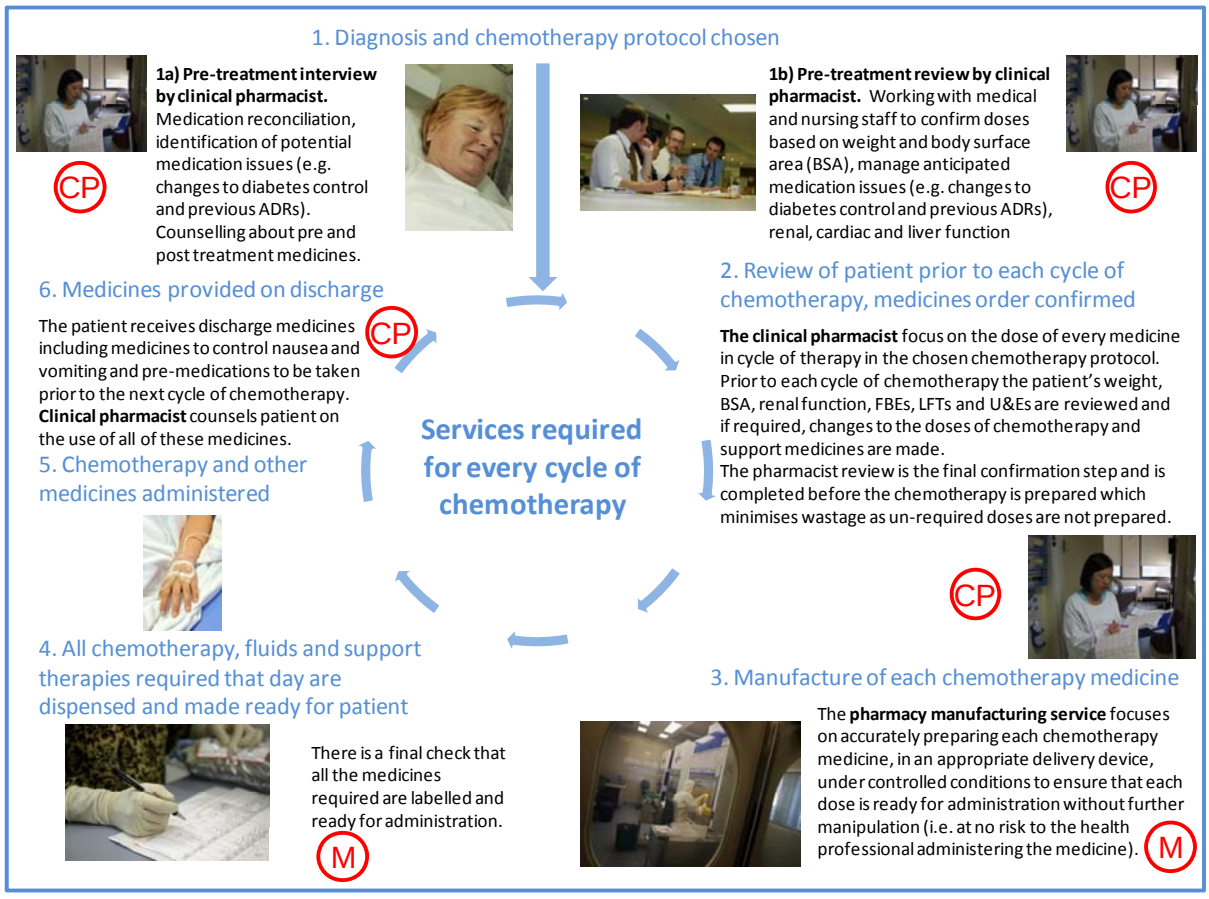
Background

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 such as docetaxel and revenue generated to fund other medicines and other pharmacy services including clinical pharmacy services for over two decades.

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 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 operating theatre facilities) have also been funded through the difference between the reimbursement and purchase price.



SHPA would like to highlight that revenue generated by hospital pharmacy services must cover the cost of providing chemotherapy medicines together with an appropriate clinical pharmacy service and infrastructure, as well as the cost of doing business with Medicare Australia.

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 and pharmacy services. Contemporary cancer services delivered via both public and private systems and into rural and regional Australia require the inclusion of a clinical services based funding model for pharmacy services.

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 assessed 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, growth factors, electrolyte replacement, hydration fluids etc.**
- **prepared for administration to minimise the risk to both the patient and the health professional preparing and 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 of these services 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 or changed 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) in line with Standard 4 of the *National Safety and Quality Health Service Standards*. http://www.safetyandquality.gov.au/wp-content/uploads/2011/09/NSQHS-Standards-Sept-2012.pdf

Pharmacy manufacturing services:

- focus on the **accurate reconstitution and preparation for each chemotherapy medicine for each individual patient**, 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).

The manufacture of the chemotherapy may occur within the pharmacy in an appropriate sterile facility or in a TGA registered facility. (In practice most pharmacy services use a mixed model.)

The costs associated with running and maintaining an appropriate sterile facility are considerable: it includes the cost of equipment and infrastructure, validation of staff and facilities, managing occupational health and safety requirements and quality assurance processes. These need to be covered by the revenue raised for providing chemotherapy medicines.

Where the actual manufacturing process is outsourced to a TGA registered facility there are additional administrative tasks for each chemotherapy dose associated with just-in-time ordering, ensuring each pre-prepared medicine is received in time for appointments, issuing of the pre-prepared medicine only after the dose has been confirmed and the work involved in either rescheduling the patient or remaking the product if the pre-ordered dose changes. Again the cost of organising each dose of chemotherapy needs to be covered by the revenue raised for providing these medicines.

Chemotherapy doses are prepared for ‘immediate use’ for administration to an individual patient the chemotherapy medicine; they have a limited expiry rather than a long shelf-life. All doses are made ‘in good faith’ the pharmacy service manufactures or sources the dose but it may not be used because of changes in the patient’s condition requiring treatment to be delayed or the dose changed.

The supply of chemotherapy medicines such as docetaxel

I. patient access to treatment

For patients to access PBS scheduled medicines through a hospital the pharmacist must understand and manage a myriad of access and funding rules on top of the legal and clinical assessment of the medication order.

The rules are different depending on where the patient is (community, hospital outpatient, same day hospital patient, hospital in the home, or overnight inpatient), whether they are being treated for an acute or chronic condition, which type of facility is providing treatment (hospital, sub-acute or non-acute facility, Aboriginal Health Service), the ownership of the facility and the ownership of the pharmacy service supplying the medicine.

The differences in the PBS authority rules for medicines to be funded through Medicare Australia, and the requirements for patient eligibility, are difficult for prescribers to identify and understand. Prescribers and pharmacists working in the hospital system must wade through eight PBS categories to supply all the medicines that may be used as part of a chemotherapy protocol (examples are shown in Appendix 1).

In addition access to PBS medicines differs between public hospitals, dependent on the pharmacy resources available at each hospital. Patients can be offered a PBS prescription that:

- can be supplied through the hospital pharmacy
- cannot be supplied as the hospital pharmacy does not offer a PBS dispensing service and must therefore be supplied through a community pharmacy.

The situation is more complex in New South Wales and the ACT where funding agreements between these jurisdictions and the Commonwealth do not include access to PBS scheduled medicines for patients treated at NSW and ACT public hospitals.

The PBS re-imbursement rules require or presume a 'no script no drug' approach. This means that in private hospitals the prescriber MUST write both a hospital medication chart and a PBS prescription for a medicine to be dispensed and payment claimed from Medicare Australia. **This requirement leads to errors and is in conflict with Standard 4 of the National Safety and Quality Health Service Standards.**

One example occurred in Adelaide in March 2011 where a patient was ordered a chemotherapy protocol. The hospital medication order for the patient included Leukeran (chlorambucil) 10mg orally for 14 days, which was reviewed by the oncology pharmacist. The doctor also wrote a separate PBS prescription for the patient's Leukeran but mistakenly ordered 6mg orally for 14 days. The incorrect dose was supplied as ordered on the PBS prescription; fortunately the error was identified and treatment failure was avoided.

The delivery of health care should be safe, effective, patient centred, timely, efficient and equitable. The current funding arrangements for chemotherapy and related medicines in hospitals cannot be said to meet these requirements.

- ✗ Unsafe work practices that increase risks to patients are required for reimbursement. A PBS prescription must be generated in addition to the medication chart.
- ✗ Patient care is delayed while prescribers and pharmacists work through administrative processes OR while the patient attends multiple doctors and pharmacies to gain access to some medicines.

- The system is a barrier to continuity of care as patients must visit multiple doctors and pharmacists to access their medicines.
- A single medicine has multiple funding rules and therefore inequity is built into the system.
- Inefficiencies are built into the system through business rules relating to authority and Section 100 medicines.
- The system can actually prevent patients from accessing some medicines.
- The value of co-payments and safety nets differ between jurisdictions.

II. cost to pharmacists and suppliers; and
III. cost to the private and public hospital systems

Pharmacies and private hospitals have been reliant on the trading terms of medicines like docetaxel and revenue generated to fund other medicines and other pharmacy services such as clinical pharmacy services for over two decades.

As noted 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. The examples shown in Appendix 1 illustrate the numerous pharmacy services that are required to ensure the safety of the patient and the optimum use of chemotherapy medicines.

In a series of papers looking at the use of the PBS in private hospitals in 2001 John Jackson detailed the problems with using the PBS in private hospitals (for inpatients and outpatients) were summarised as:

1. “Lack of integration between standard PBS operating procedures and hospital practices.
2. The lack of tailoring of the PBS drug range and quantities to hospital requirements.
3. The fact that pharmacy remuneration is solely related to supply with no regard given to the particular requirements of caring for the hospitalised patient.

The problems are illustrated by:

- Prescriptions not being written when required resulting in outstanding prescriptions
- If and when written, the manner in which they are written and the details provided are often not compliant with PBS requirements
- The amount of medication able to be dispensed on any one occasion may not be adequate for the circumstance of use and restrictions on the frequency of repeat dispensing are often inappropriate
- Illogical regulations relating to authorities to prescribe increased quantities
- Difficulties in complying with arrangements for obtaining approval to prescribe and dispense authority listed drugs
- Drugs essential for hospital treatment not being included in the PBS Schedule
- The clerical demands on pharmacy to process prescriptions being unduly burdensome and more so when prescriptions are outstanding
- The lack of reimbursement for professional tasks related to hospital practices associated with particular drugs and

- The lack of reimbursement for the clinical role of the pharmacist in contributing to appropriate use of medicines."

More than a decade on, any objective review of the PBS in Australia's hospitals would list the same issues associated with patient care, the safe use of medicines, access, inefficient processes and reimbursement.

This is why the Efficient Funding of Chemotherapy for public hospitals program should be offered to all private hospital pharmacy providers.

For patients to access PBS scheduled medicines (including chemotherapy medicines) through a hospital the pharmacist must understand and manage the following:

- The list of medicines on the PBS
- Any specific requirements for access to that medicine
- The amount of the medicine that can be supplied and how frequently it can be supplied
- When the medicine can be supplied to the patient through the PBS and when it must be supplied outside the PBS
- Which brand of the medicine is required / suitable and the impact of that choice on the cost to the patient
- How to apply for / confirm authority requirements for each of the eight authority categories:
  - Section 85 authority medicines (e.g. Anzatax injection)
  - Section 85 authority required for access to increased quantities of medicines listed as restricted benefits (e.g. Solu-Medrol injection where more than one dose is required)
  - Section 85 authority 'streamlined' (e.g. Gantin capsules)
  - CPAP listed medicines available only through public hospitals (e.g. Fludara injection)
  - S100 highly specialised drugs (HSD) authority medicines, public hospitals (e.g. Mabthera injection)
  - S100 HSD authority medicines, private hospitals (e.g. Neoral liquid)
  - S100 HSD authority 'streamlined' medicines available only through public hospitals (e.g. Neupogen injection)
  - S100 HSD Complex Authority Required medicines, public hospitals (CAR HSD) (e.g. Herceptin)
- Rules about the size and format of the prescription form that must be used for different PBS categories
- Rules about prescribers eligible to prescribe scheduled medicines and prescribers eligible to prescribe medicines that may be supplied through the PBS
- Rules about patient eligibility specifically if the patient is eligible for benefits through Medicare
- Rules about the patients financial contribution including if the patient is eligible for a concession card, if the patient has met safety net arrangements
- Rules about accessing medicines through the 'closing the gap' system

- Rules about claiming reimbursement for the supply of the medicines including the appropriate prescription form, compliance with formatting, compliance with details required (dependent on PBS category) and compliance with indications and PBS listings
- Which claiming process is required for each PBS category (manual, electronic or a combination) and the data requirements for each category
- If the patient is eligible for 'Closing the Gap' funding

All of these are ADDITIONAL to the usual considerations required for the safe and effective supply of medicines; whether:

- The medicine order is legible and meets legal requirements
- There is a clear indication for the medicine
- The dose and frequency appear to be appropriate for that indication
- The dose form is appropriate for that patient
- There are no contraindications including previous allergies, adverse medicine events or concurrent clinical conditions
- The patient has been taking the medicine as prescribed
- The medicine is currently achieving the goals of therapy
- There are any medicines that have been inadvertently omitted
- There has been appropriate monitoring of the medicine
- There are detrimental interactions with other medicines or food
- There is a duplication of medicines
- If polypharmacy (the use of multiple medicines) is an issue

Claims for PBS medicines are refused if:

- The patient's name and address is not written by the doctor
- If the doctor uses a hospital generated label that does not have an address listed or they do not appropriately annotate the label
- The pharmacy has added details using a computer generated label with full details
- The patient's agent signs for the prescription without adding the correct wording regarding the reason the patient cannot collect the medicine themselves.

The administrative burden for pharmacists and the number of funding mechanisms and categories within the PBS continue to expand. Further problems are created when new government policy is developed that further entrenches and promulgates the old problems. Layer upon layer of waste-causing activities compound and accumulate until a high proportion of what is done is non-value adding. **As noted earlier revenue generated by the pharmacy must cover the cost of doing business with Medicare Australia, antiquated business rules are adding to this cost.**

In addition, opportunities to improve how medicines are provided have been lost. For example changes to work practices in hospitals driven by the introduction of a national inpatient medication chart (NIMC) and associated medicine charts offers an opportunity to redesign the processes required for medicines to be supplied through the PBS to same day and overnight inpatients in both public and private hospitals nationally.

The PBS was not set up to support the use of medicines in hospitals. Business rules from 1947 on the way a prescription must be written for reimbursement continue to drive how doctors and pharmacists provide services to patients in 2013.

The requirement for a separate hardcopy PBS prescription means that doctors must write two orders (e.g. discharge prescription for all medicines and multiple PBS prescriptions) for patients in private hospitals. This leads to errors and reduced patient safety.

Patients may not receive medicines in a timely manner whilst who is responsible / able to write the PBS prescription is being clarified. In practice, doctors make the decision to initiate or change a medicine when seeing the patient; bureaucratic requirements are considered later. A considerable proportion of pharmacists', doctors and nurses time is spent meeting these bureaucratic requirements; this reduces time spent on direct patient care and is not conducive to positive collaboration between these health care professionals.

The high cost of many chemotherapy medicines means that there is considerable financial risk to the hospital / pharmacy when providing treatment without knowing / confirming that the cost of the chemotherapy will be reimbursed. **In hospitals that specialise in cancer services the potential financial risk runs into the hundreds of thousands of dollars.**

In practice this means that in private hospitals chemotherapy treatment is delayed until funding can be confirmed (i.e. authority to prescribe is granted through Medicare Australia and an appropriate prescription is received).

The financial risk in public hospitals has been minimised by the introduction of the Efficient Funding of Chemotherapy for public hospitals program.

This is a photo of **one week's worth** of prescriptions generated from inpatient medication charts through a Section 94 pharmacy at a private hospital. All of the medicines have already been ordered on the patient's hospital medication chart and have already been supplied. **This paperwork shown is additional and required only for the pharmacy to make a claim to Medicare Australia.**

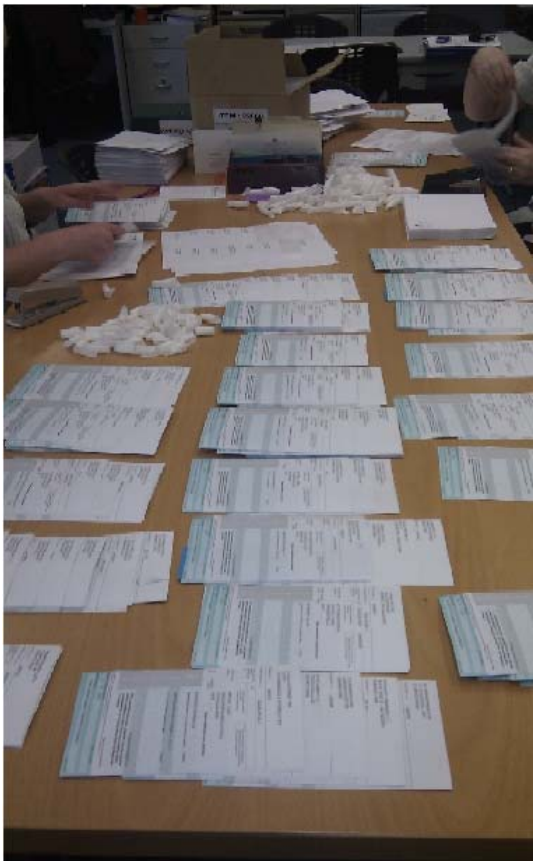
A major initiative to improve the safe use of medicines is the standardisation of medication ordering in hospitals through the NIMC. A common medication chart in use in all Australian public hospitals by June 2006 was required by Health Ministers in April 2004.

The improvements in medication safety associated with the NIMC are problematic in private hospitals as use of the standard NIMC requires that doctors write both the medication order and another PBS prescription.

As shown in the picture below from another hospital pharmacy each of these additional prescriptions must be:

- printed on approved PBS stationery obtained from authorised prescribers
- sorted, the relevant prescriber must be identified and the hardcopy prescription then must be sent to that prescriber
- signed by the prescriber
- sent back to the pharmacy and
- processed for claiming through Medicare Australia
- filed and stored separate from the patient's medical history for audit requirements

Frequently the pharmacy needs to reprint several hard copies of the prescription before it is signed by the prescriber.



When the doctor returns the signed prescription, the PBS sticker required to claim for the medicine can be attached. Each prescription is produced in triplicate:

1. one kept in archives or attached to the repeat;
2. one for PBS claim copy;
3. one put into the patient's medical history / permanent record.

The copies are then sorted into four piles (general, concession, entitlement, repatriation) in numerical order of PBS claim sticker ready for submission to Medicare Australia.

Private hospitals have informed SHPA that they anticipate a time period of up to **six months** between supply of the medicine and receipt of a signed prescription for claiming by the pharmacy. This issue is of greater concern when a PBS authority is required for the medicine; where the anticipated time period is up to **twelve months** between supply of the medicine and receipt of a signed prescription for claiming by the pharmacy. There are also considerable difficulties when a patient has died during the admission having received medicines before the PBS prescriptions or authorities have been formalised.

All of this additional paperwork is only required so that the pharmacy can make a claim to Medicare Australia. As noted earlier revenue generated by the pharmacy / hospital must cover this cost of doing business with Medicare Australia.

In 1998 Medicare Australia initiated a *Paperless Claiming Trial* in a handful of private hospitals. SHPA understands that after 15 years this trial continues in pharmacy services in seven private hospitals in Victoria.

SHPA believes that after a 15 year trial Medicare Australia should be in a position to move paperless claiming to 'business as usual' for all Section 90 and Section 94 pharmacy services that provide services to private hospitals.

Principles for a long-term, sustainable funding model for the supply 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 including the cost of doing business with Medicare Australia
- 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 for the clinical pharmacy services that support the safe use of these toxic medicines.

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 patients
- remove the need for 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 provided 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 pharmacist review process that occurs prior to a course of chemotherapy being prescribed and the clinical pharmacist 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 pharmacist 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.

SHPA's model for 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 to fund chemotherapy medicines and chemotherapy services supports equity of access across the country and is equally applicable across all hospitals / types of pharmacy services and whether or not the medicine is prepared in the on-site pharmacy or by a TGA licensed facility.

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 both Section 90 and Section 94 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 of a specific professional organisation, or the profit / not-for-profit status of the pharmacy service as it is currently. **Government funding should be contingent upon services required by individual patients, patient eligibility and the services actually delivered by the pharmacy service.**

1. 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 outdated as it 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/ps_cyto_handling.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. However, many chemotherapy medicines are reconstituted, diluted and transferred to another container and provided in a ready-to-use form, which may incur 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, building and maintaining the required sterile room infrastructure, 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 the on-site pharmacy or by a TGA licensed facility.

2. Funding of professional pharmacy services

SHPA notes that the 5th Community Pharmacy Agreement (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 patients 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 patient. 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 patients 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 patients 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.

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 receives will require close monitoring of her blood glucose levels which may lead to changes to her usual medicines (which will be impacted on 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.

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)

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

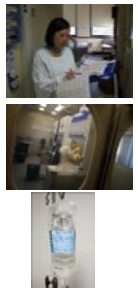
The treatment protocol for each cycle of chemotherapy comprises of:

- 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)

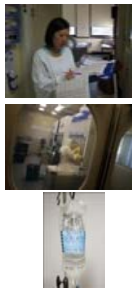
Cycle 1 (day 2)



- 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)

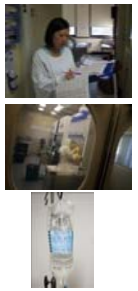
Cycle 2 (day 29)



- 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)

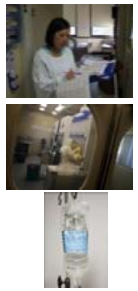
Cycle 3 (day 57)



- 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)

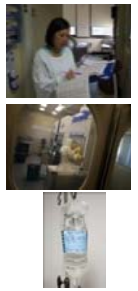
Cycle 4 (day 85)



- 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)

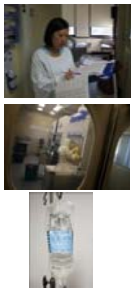
Cycle 5 (day 113)



- 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. predicting and recommending 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 pharmacies providing services to private hospitals and Section 94 private hospital pharmacy services 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.