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Dear Professor Wilson

Recommended additions to the Pharmaceutical Benefits Scheme Prescriber Bag

The Royal Australian College of General Practitioners (RACGP) is Australia's largest general practice organisation, representing more than 40,000 members working in or towards a career in general practice.

In letters dated February and August 2018, the RACGP provided the Pharmaceutical Benefits Advisory Committee (PBAC) with the outcomes of our review of the contents of the Pharmaceutical Benefits Scheme (PBS) Prescriber Bag. In August 2019 the PBAC Secretariat offered the RACGP an opportunity to reconsider our previous advice. The RACGP thanks the PBAC for this opportunity.

As per our earlier letters, the RACGP asserts that better use of primary care will reduce emergency department presentations and hospital admissions, which will lead to significant savings for the health system.[1-8] This can be achieved, in part, through our recommended update to the contents of the PBS Prescriber Bag. With the appropriate support, general practitioners (GPs) are ideally placed to provide early, cost-effective interventions for urgent cases when access to a pharmacy is restricted, for example after-hours or in rural and remote areas.

Our review of the PBS Prescriber Bag provisions highlighted that medicines for the urgent management of heart failure and acute infections outside of the hospital setting are not included. Currently, GPs must bear the cost of supplying these medications for emergency use. We present two options for adding medications to the PBS Prescriber Bag (*appendix 1*) to assist in improved management of urgent cases in the community setting.

If you would like to discuss our recommendations further, please contact Madeleine Senior, Program Manager, Funding and Health System Reform, via madeleine.senior@racgp.org.au or 03 8699 0524.

Yours sincerely

Dr Harry Nespolon
President

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Appendix 1

Additions to the PBS Prescriber Bag

1. Background

The RACGP has reviewed the contents of the PBS Prescriber Bag and has identified that there is an immediate need for medicines to be added to manage acute and urgent pre-hospital treatment for heart failure, urinary tract infections and cellulitis. These issues are common and account for a large proportion of potentially preventable hospitalisations (PPHs) in Australia.[1] The inclusion of these additional medicines would enable GPs to treat people in the community and resolve urgent problems before they require more intensive treatment and/or treatment in the hospital setting.

2. Recommendation

The RACGP recommends that the PBAC add to the PBS Prescriber Bag several safe and effective oral medicines which facilitate the urgent pre-hospital management of heart failure and acute infections.

2.1 Details of the recommendation

Two options are presented for adding medicines to the PBS Prescriber Bag. The RACGP supports the adoption of Option 2 as it better aligns with the *Therapeutic Guidelines* for the treatment of acute urinary tract infections.

Option 1

Option 1 includes three medicines for addition to the PBS Prescriber Bag (table 1).

Table 1. RACGP recommendations (option 1) for addition to the PBS Prescriber Bag

Medicine	Strength	Max qty per patient for emergency use	Indications
Oral frusemide	40mg	10 tablets	• Congestive heart failure • Ascites in palliative care
Oral cefalexin	500mg	10 tablets	• Empirical therapy for acute cystitis in pregnancy • Acute pyelonephritis • Empirical therapy for cellulitis and erysipelas without systemic features • Impetigo in non-endemic settings • Lactational mastitis • Empirical therapy for superficial surgical site infections
Oral trimethoprim	300mg	7 tablets	• Empirical therapy for non-pregnant women with acute cystitis • Empirical therapy for men with acute cystitis • Empirical therapy for children with acute cystitis or acute pyelonephritis

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Option 2

Option 2 sets out four medications for addition to the PBS Prescriber Bag (table 2).

Table 2. RACGP recommendations (option 2) for addition to the PBS Prescriber Bag

Medicine	Strength	Max qty per patient per patient for emergency use	Indications
Oral frusemide	40mg	10 tablets	• Congestive heart failure • Ascites in palliative care
Oral cefalexin	500mg	10 tablets	• Empirical therapy for acute cystitis in pregnancy • Acute pyelonephritis • Empirical therapy for cellulitis and erysipelas without systemic features • Impetigo in non-endemic settings • Lactational mastitis • Empirical therapy for superficial surgical site infections
Oral trimethoprim	300mg	7 tablets	• Empirical therapy for non-pregnant women with acute cystitis • Empirical therapy for men with acute cystitis • Empirical therapy for children with acute cystitis or acute pyelonephritis
Oral nitrofurantoin	100mg	24 tablets	• Empirical therapy for acute cystitis in pregnancy • Empirical therapy for acute cystitis in adults, previously treated with trimethoprim in past 3 months and/or with a history of trimethoprim-resistant *E. coli* infection

2.2 Preferred treatment for urgent heart failure

The addition of oral frusemide to the Prescriber Bag is included in both options.

Frusemide is a diuretic which is widely recognised as appropriate and effective for the management of fluid retention associated with heart failure.[2] The *Therapeutic Guidelines* recommend oral furosemide as an appropriate loop diuretic for reducing the signs and symptoms of congestion in patients experiencing heart failure with reduced ejection fraction.[3] Guidelines for heart failure developed by the National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand also recommend frusemide for fluid management in chronic heart failure.[4]

Frusemide is the most commonly prescribed medicine for managing chronic heart failure in Australia.[5] Patients who have their frusemide levels adjusted following heart failure show a reduction in clinical symptoms and are less likely to be admitted to the emergency department.[4,6]

Frusemide may also be used to treat ascites in palliative care patients.[7]

The RACGP acknowledges that frusemide is currently available through the PBS Prescriber Bag as an injectable; however, oral medication may be more appropriate in many situations, as discussed in more detail in section 3.3.

2.3 Preferred treatment for urgent acute infections

Option 1 recommends listing cefalexin for its broad application for a range of infections, including to treat urinary tract infections in pregnant women, and trimethoprim for urinary tract infections in non-pregnant women, men and children. Option 2 also includes nitrofurantoin, aligning with the current *Therapeutic Guidelines* on the management of acute cystitis in pregnant women and in those recently treated with trimethoprim or with a history of trimethoprim-resistant *E. coli* infection.[8]

Cefalexin

Cefalexin is a safe option for management of a range of infections with a higher likelihood of serious complications.

The *Therapeutic Guidelines*[8] recommend the use of oral cefalexin for the treatment of cellulitis and erysipelas in patients with non-severe hypersensitivity to penicillins. Cefalexin is also appropriate for the treatment of pyelonephritis, mastitis, impetigo and superficial surgical site infections. It can also be used to treat cystitis. The *Therapeutic Guidelines* recommend treatment, depending on condition and age, every 6-12 hours for 3-14 days.

Trimethoprim

Trimethoprim is recommended by the *Therapeutic Guidelines*[8] as an appropriate first line treatment for urinary tract infections for non-pregnant women, men and children. Trimethoprim may also be used in the second and third trimesters of pregnancy. It is recommended that it is taken daily in adults and 12-hourly in children for between 3 and 14 days, depending on condition, age and sex.

Including trimethoprim in the PBS Prescriber Bag will reduce the frequency of use of cefalexin, which requires a more frequent dosage and, depending on condition, age and sex, a longer treatment period for urinary tract infections. For this reason, the RACGP recommends trimethoprim as the preferred treatment for urinary tract infections.

Nitrofurantoin

Nitrofurantoin is recommended as first line therapy for the management of acute cystitis in pregnant women (6-hourly for five days), as per the *Therapeutic Guidelines*.[8] It is also appropriate for the treatment of cystitis in non-pregnant women and men recently treated with trimethoprim and/or with a history of trimethoprim-resistant *E. coli* infection.

2.4 Antibiotic resistance

The RACGP sees antimicrobial resistance as a national priority and has carefully considered the consequences of adding oral antibiotics to the Prescriber Bag. Where possible, the RACGP does not recommend the use of broad-spectrum antibiotics when narrow-spectrum would suffice.

General practice has a major role to play in maintaining antibiotic effectiveness, as well as educating the public on the appropriate antibiotic use and emerging resistance. The RACGP is committed to helping GPs to deal with expectations, change management and implementing new initiatives to reduce antibiotic usage where safe to do so.

The addition of cefalexin, trimethoprim and nitrofurantoin (if option 2 were preferred) to the PBS Prescriber Bag will not increase antibiotic use in the community, as patients who present to a general

practice with an acute infection will be treated with antibiotics. The benefit of adding these antibiotics to the PBS Prescriber bag is timely treatment and the avoidance of second line antibiotics. Failure to treat acute infections at an early stage in the community setting may result in hospital presentations, longer duration of treatment and/or the use of second line antibiotics, combinations of antibiotics and IV antibiotics.

2.5 Quantities specified

The quantities detailed are sufficient for emergency access for a single patient/occasion only, aiming to ensure that the patient can receive safe and effective treatment early and quickly, thereby preventing deterioration and subsequent use of more intensive treatments and/or hospital services. A follow-up visit with a GP and/or to a pharmacy to obtain the full course of treatment will still be required. Quantities specified are based on the most intensive regime for each medicine, as indicated by the relevant guidelines.

The recommendations on medicine quantities rely solely on clinical guidance. The RACGP has not recommended pack sizes or pack numbers to include in the Prescriber Bag. We anticipate providing further advice on these matters as part of the Department of Health's change process, with a view to ensuring a cost efficient solution which meets identified needs.

3. Rationale for recommendation

3.1 Reducing potentially preventable hospitalisations

Heart failure and acute infections are amongst the most commonly reported PPHs.[1] These hospitalisations can largely be reduced with adequate and timely care in the community and via primary care,[9] including the general practice setting. The RACGP has estimated the cost of PPHs for heart failure, urinary tract infections and cellulitis in Australia at $870m a year.[i]

Patients who experience a PPH stay an average of 4 days in the hospital. In 2017-18, 748,000 PPHs accounted for 2,972,878 bed days.[1] This is a significant cost to the hospital system and the economy.

In 2017-18, urinary tract infections (including pyelonephritis) caused nearly 77,000 PPHs, cellulitis led to nearly 69,000 PPHs and congestive heart failure caused over 62,000 PPHs.[1] Cellulitis and heart failure were also amongst the most common reasons for admission to hospital following presentation at an emergency department in 2018-19.[10] A large majority of these presentations were classified as urgent or semi-urgent, ie not emergency or resuscitation.

Equipping GPs with the appropriate medicines to treat common urgent conditions in the community setting when pharmacy services are unavailable will assist in reducing the number of presentations to emergency departments and overall PPHs. This can both help ensure that care can be provided to other hospital patients sooner and deliver significant savings to the Australian healthcare system

3.2 Areas of significant need

The need to manage urgent conditions when patients present at a general practice is especially important in circumstances where it is not possible for patients to attend a pharmacy. This is particularly relevant for urgent care provided:

- outside of standard pharmacy business hours

[i] Number of PPHs 2017-18[1]*average cost per admission 2011-12[17]

- in rural and remote areas, where there is often a significant distance to travel to the closest pharmacy and pharmacy business hours may be more restricted
- during home, institution or residential aged care facility visits, where patients have already been deemed to have significant mobility issues and are unable to travel to the general practice and/or a pharmacy
- to patients with medication adherence issues, where a GP determines it unlikely that a patient will attend a pharmacy to retrieve their urgent prescription.

Chronic heart failure, skin infections and urinary tract infections have a relatively high prevalence in general practice.[5,11-13] It is common for GPs to see patients with these urgent conditions in the situations outlined above.

3.3 The need for oral alternatives for the management of urgent conditions

Most medicines available through the PBS Prescriber Bag are ampoules for injection. While ampoules are useful in emergencies where the patient is likely to be admitted to hospital and receive further monitored medication management, they are limited in their use for urgent care in the community.

Oral medicines are important for managing urgent care when a patient needs to begin their medication immediately and requires more than one dose. In circumstances where patients require administration of medicine multiple times a day and/or for a number of days, it is extremely inefficient and expensive for a GP to return to see a patient or for a patient to repeatedly present at the practice to receive their required medicine via injection, especially when suitable oral equivalents are readily available.

Evidence has shown that oral medications are often just as effective as injectables.[14,15] In addition, oral medicines have a lower risk to the patient as intravenous medicines can result in phlebitis, thrombosis, extravasation injury, localised infection and bacteraemia.

3.4 The significance of the PBS Prescriber Bag in general practice

GPs are the primary users of the PBS Prescriber Bag. It is mandatory for all accredited general practices to ensure that their GPs have access to a fully equipped doctor's bag during home/institution visits or in an emergency.[16] The PBS Prescriber Bag provisions are used to stock a practice's doctor's bag.

If practices wish to have medicines in their doctor's bag that are not available through the PBS Prescriber Bag provisions, they must be provided to patients at the practice's expense. This is unaffordable for many practices as maintaining private supplies of medications is costly. As such, patient out of pocket costs may increase and become a barrier to patients seeking care. Therefore, it is essential that the contents of the PBS Prescriber Bag allow for sufficient management of common urgent conditions that are likely to require hospital attention if not treated immediately.

Currently, if patients visit their GP with an urgent issue such as heart failure or an acute infection, GPs must write a prescription for the patient to retrieve medicines from a pharmacy. However, it is not always convenient or possible for patients to access a pharmacy in these urgent circumstances. As a result, these patients are often treated in the hospital setting – which is not always clinically necessary, is more expensive for the health system and uses already stretched hospital and emergency department resources.

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