

Agenda Item 11.07

Antibiotic Repeats on the Pharmaceutical Benefits Scheme

1 Purpose of Item

- 1.1 As part of a broader body of work to improve antibiotic use in Australia, the Department of Health (the Department) undertook a review of antibiotic listings on the Pharmaceutical Benefits Scheme (PBS) that allowed repeat prescriptions to be issued automatically.
- 1.2 The aim of the review, and the resultant request to the Pharmaceutical Benefits Advisory Committee (PBAC) for consideration (the Request), was to support health professionals to engage in antimicrobial stewardship and prescribe antibiotic repeats only when clinically indicated, thus reducing inadvertent repeat prescribing when initiating a course of antibiotics.
- 1.3 The Request did not intend to impede health professionals' ability to prescribe antibiotic repeats when clinically indicated.

2 Summary of the Request

- 2.1 The Request was drafted to take into consideration the stakeholder feedback that was within the scope of the Request, and the indications listed in the current version of the *Therapeutic Guidelines* (version 16)¹.
- 2.2 The Request included only the top five antibiotics (amoxicillin, amoxicillin with clavulanic acid, cefalexin, doxycycline and roxithromycin) where repeats were dispensed by volume on the PBS. These five antibiotics represent 78% of all repeats prescribed on the PBS. It was noted that of the 4,481,050 repeat antibiotic prescriptions supplied through the PBS, approximately one in five were dispensed more than 30 days after the original prescription was dispensed.
- 2.3 The Request did not consider issues relating to quantity available (pack size), the need for additional repeats, broadening of indications for existing listings or the removal of existing restrictions, even though these may be required to align the PBS listings more completely with the *Therapeutic Guidelines* (version 16).
- 2.4 The Request proposed to restrict relevant listings, using Authority Required (STREAMLINED) options to encourage clinicians to prescribe repeats of these antibiotics only when clinically indicated as per the *Therapeutic Guidelines* (version 16).
- 2.5 The Department will communicate the agreed changes to prescribers through a variety of mechanisms and conduct post-implementation monitoring to identify any

¹ The *Therapeutic Guidelines* are a collection of guidelines published by an independent not-for-profit organisation in Australia, specifically to provide clear, practical and up-to-date information to prescribers. The *Therapeutic Guidelines* are endorsed by many reputable organisations and peak bodies, in addition to being used commonly in public teaching hospitals, and community medical and pharmacy practices in Australia.

unintended consequences to patient care and clinicians' prescribing behaviour.

3 Background

- 3.1 In April 2018, the PBAC agreed to the Department undertaking a review of antibiotic listings on the PBS; and where appropriate, proposing changes to individual listings to restrict or remove access to repeats.
- 3.2 In late 2018, the Department provided a consultation paper, proposing changes to individual antibiotic listings based on indications outlined in the *Therapeutic Guidelines* (version 15), to key stakeholders for consideration². Responses were largely supportive with 15 of 23 (65%) stakeholder groups responding.
- 3.3 In April 2019, following the initial stakeholder consultation, the *Therapeutic Guidelines* (version 16) was published. The Department updated its proposed changes based on the updated *Therapeutic Guidelines* (version 16) where necessary. The Department did not undertake a revised stakeholder consultation on these changes as the broadening of indications resultant from the updates to the *Therapeutic Guidelines* (version 16) aligned with the feedback received in late 2018. In June 2019, the Department conducted a Sponsor consultation on the proposed changes. Feedback was received from two (of eleven) Sponsors. One Sponsor was neutral to the proposed changes. The other Sponsor made a recommendation for several listings, however their recommendations would not be consistent with the *Therapeutic Guidelines* (version 16).
- 3.4 The Department is aware of a number of additional issues related to antibiotic listings on the PBS but these are not within the scope of this Request.

4 PBAC Outcome

- 4.1 The PBAC considered the changes proposed in the Request for advice from the Minister's delegate and recommended changes to the antibiotic PBS items which allow prescriptions for amoxicillin, amoxicillin and clavulanic acid, cefalexin, and roxithromycin as below (and detailed in section 5):
 - implementing new Authority Required (STREAMLINED) listings to enable access to antibiotic prescriptions with repeats for indications where clinically indicated as per the *Therapeutic Guidelines* (version 16);
 - for some listings, amending the maximum quantity and repeats to enable a full recommended course of antibiotic treatment for a specific indication, as recommended in the *Therapeutic Guidelines* (version 16), to be dispensed in one prescription for short courses of treatment; and
 - maintaining access for indications not listed in the *Therapeutic Guidelines* (version 16), without repeats, by maintaining or adding unrestricted listings for shorter

² Respondents included the Royal Australian College of General Practitioners, Australian Medical Association and the Australian College of Rural and Remote Medicine, amongst other professional organisations.

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courses of treatment, with the inclusion of an administrative note that no repeats or increases in maximum quantity are permitted.

- 4.2 The PBAC did not recommend changes to any PBS listings for doxycycline as they already aligned with the *Therapeutic Guidelines* (version 16) regarding indications and treatment periods. The PBAC noted that the Request had not suggested any changes to doxycycline listings such as increasing the maximum quantity of supply without a repeat, and considered that it was not currently able to make a recommendation on this as no analysis of potential changes had been provided.
- 4.3 The PBAC did not recommend any changes to the Authority Required (STREAMLINED) listing for cefalexin 250 mg for use in prophylaxis of urinary tract infection, and cefalexin 500 mg for use in treating osteomyelitis. The PBAC considered both listings aligned with the current *Therapeutic Guidelines* (version 16).
- 4.4 The PBAC did not recommend any changes to the listing of amoxicillin 1 g, for restricted use in chronic bronchitis, because the indications under the *Therapeutic Guidelines* (version 16) for this listing were broadened since the last edition, but the purpose of the Request was not to broaden restrictions. However, the PBAC considered that this listing should be part of a future review.
- 4.5 The PBAC considered that there have been shortages of flucloxacillin that have caused an increase in the use of cephalexin for treating cellulitis.
- 4.6 The PBAC noted that current use of roxithromycin is high. The PBAC considered that most of the use is likely to not be consistent with the *Therapeutic Guidelines* (version 16) and that removing the repeats will reduce unnecessary overuse of roxithromycin.
- 4.7 The PBAC noted the intent of the Request, and that it supported the promotion of antimicrobial stewardship and aligning PBS indications with the *Therapeutic Guidelines* (version 16). The PBAC also noted the consultation that had been undertaken and the input received during consultation. The PBAC noted that the Request focused on five antibiotics with high volume dispensing and repeats, and that the proposed changes would remove PBS-listed access to repeat prescriptions for indications not listed in the *Therapeutic Guidelines* (version 16).
- 4.8 The PBAC noted that the scope of the Request was to consider amendments to antibiotic listings with repeats to improve antibiotic use and reduce inadvertent repeat prescriptions, and that broader changes to promote antimicrobial stewardship are complex due to pack size inconsistencies across indications and products. The PBAC noted that as a result, its recommendations would more closely, but not necessarily completely, align the associated PBS listings with the *Therapeutic Guidelines* (version 16).
- 4.9 The PBAC noted the risk of a transfer to private prescriptions as the price of many antibiotics outside the PBS is within the range of, or under, the co-payment. Accordingly, the PBAC noted that a strong program of education and support for

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prescribers and other stakeholders would be required by the Department to drive support for the changes.

- 4.10 The PBAC considered implementation of Authority Required (STREAMLINED) listings would support the intent of the Request, in encouraging the prescribing of appropriate courses of treatment for a presenting condition without significantly increasing prescriber workload.
- 4.11 The PBAC noted the Request had considered that access to some antibiotic listings without repeats, via unrestricted listings, may still be clinically valuable and should remain in place. The PBAC considered this to be appropriate, and accordingly that existing unrestricted listings would remain in place with administrative notes to limit repeats, and that new listings for specific indications to be added to the PBS.
- 4.12 PBAC noted that if there were a clinical need for a patient meeting the indications for a restricted listing to receive a longer course of treatment, that there would still be an option for prescribers to seek an authority via Services Australia. However, the PBAC considered that no increase in maximum quantity or repeats be allowable for all reviewed unrestricted items to ensure alignment with the intent of the changes, and to align longer treatment courses with the *Therapeutic Guidelines* (version 16). The PBAC noted that although this limits treatment course duration for PBS items, clinicians may still choose to prescribe longer courses, or for different indications, outside of the PBS.
- 4.13 The PBAC noted that these recommendations more closely aligned PBS listings for the antibiotics considered with the *Therapeutic Guidelines* (version 16), however future updates to the *Therapeutic Guidelines* may impact alignment, and similarly antibiotic listings not considered in the Request may not align with the guidelines currently.
- 4.14 The PBAC noted that prescribers have to pay a fee to access the *Therapeutic Guidelines* (version 16) due to it being independent and not receiving any government funding. However, the PBAC considered it a commonly accessed resource, along with other commonly used resources in practice that also require a fee for access.

Summary of PBAC Recommendations for Antibiotic Listings

Amoxicillin				
<u>Listing 1884E</u>				
Formulation: amoxicillin - capsule 250mg (as trihydrate)				
	Current listing:	Proposed new listing:	PBAC Recommended amendment:	PBAC Recommended new listing:
Max quantity	20	20	20	40
Repeats	1	0	0	0
Qty issued	40	20	20	40

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with repeat				
Restriction	Unrestricted	Unrestricted	Unrestricted	Authority Required (STREAMLINED) for: <ul style="list-style-type: none"> • Conditions where prolonged oral antibiotic therapy is required
<p>Listing 1889K Formulation: amoxicillin - capsule 500mg (as trihydrate)</p>				
	Current listing:	Proposed new listing:	PBAC Recommended amendment:	PBAC Recommended new listing:
Max quantity	20	20	20	40
Repeats	1	1	0	0
Qty issued with repeat	40	40	20	40
Restriction	Unrestricted	Authority Required (STREAMLINED) for: <ul style="list-style-type: none"> • Men with acute cystitis • Non-severe pyelonephritis in non-pregnant adults • Tooth avulsion • Salmonella enteritis • Conditions where prolonged oral antibiotic therapy is required following initial intravenous antibiotic therapy 	Unrestricted	Authority Required (STREAMLINED) for: <ul style="list-style-type: none"> • Acute cystitis in men • Pyelonephritis • Tooth avulsion • Salmonella enteritis • Conditions where prolonged oral antibiotic therapy is required

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<u>Listing 08581P</u>				
Formulation: amoxicillin - tablet 1g (as trihydrate)				
	Current listing:	Proposed new listing:	PBAC Recommended amendment:	PBAC Recommended new listing:
Max quantity	14	NO CHANGE RECOMMENDED	Nil	14
Repeats	1		N/A	1
Qty issued with repeat	28		N/A	28
Restriction	Restricted for: <ul style="list-style-type: none"> Chronic bronchitis 		N/A	Authority Required (STREAMLINED) for: <ul style="list-style-type: none"> Community acquired pneumonia

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Amoxicillin + clavulanic acid				
Listing 1891M				
Formulation: amoxicillin + clavulanic acid - tablet 500mg amoxicillin (as trihydrate) with 125mg clavulanic acid (as potassium clavulanate)				
	Current listing:	Proposed new listing:	PBAC Recommended amendment	PBAC Recommended new listing:
Max quantity	10 (20 including repeat)	10 (20 including repeat)	10	20
Repeats	1	1	0	0
Restriction	Restricted for: <ul style="list-style-type: none"> infections where resistance to amoxicillin is suspected infections where resistance to amoxicillin is proven 	Authority Required (STREAMLINED) for: <ul style="list-style-type: none"> Acute cystitis in men 	Restricted for: <ul style="list-style-type: none"> infections where resistance to amoxicillin is suspected infections where resistance to amoxicillin is proven 	Authority Required (STREAMLINED) for: <ul style="list-style-type: none"> Acute cystitis in men Conditions where prolonged oral antibiotic therapy is required
Listing 8254K				
Formulation: amoxicillin + clavulanic acid - tablet 875mg amoxicillin (as trihydrate) with 125mg clavulanic acid (as potassium clavulanate)				
	Current listing:	Proposed new listing:	PBAC Recommended amendment:	PBAC Recommended new listing:
Max quantity	10	10	10	20
Repeats	1	1	0	0
Qty issued with repeat	20	20	10	20

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Restriction	<p>Restricted for:</p> <ul style="list-style-type: none"> infections where resistance to amoxicillin is suspected infections where resistance to amoxicillin is proven 	<p>Authority Required (STREAMLINED) for:</p> <ul style="list-style-type: none"> Periorbital (preseptal) cellulitis. Non-severe postpartum endometritis Exacerbations of bronchiectasis Non-severe pyelonephritis in non-pregnant adults Pneumonia Diabetic foot infection Conditions where prolonged oral antibiotic therapy is required following initial intravenous antibiotic therapy 	<p>Restricted for:</p> <ul style="list-style-type: none"> infections where resistance to amoxicillin is suspected infections where resistance to amoxicillin is proven 	<p>Authority Required (STREAMLINED) for:</p> <ul style="list-style-type: none"> Periorbital (preseptal) cellulitis Postpartum endometritis Exacerbations of bronchiectasis Pyelonephritis Pneumonia acquired in hospital or aged care Diabetic foot infection Conditions where prolonged oral antibiotic therapy is required
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Cefalexin				
<u>Listing 2655R</u>				
Formulation: cefalexin - capsule 250mg (anhydrous)				
	Current listing:	Proposed new listing:	PBAC Recommended amendment:	PBAC Recommended new listing:
Max quantity	40	NO CHANGE RECOMMENDED	Nil	NO CHANGE RECOMMENDED
Repeats	2		N/A	
Qty issued with repeat	120		N/A	
Restriction	Authority Required (STREAMLINED) for: <ul style="list-style-type: none"> Prophylaxis of urinary tract infection 		N/A	
<u>Listing 10778G</u>				
Formulation: cefalexin - capsule 500mg (anhydrous)				
	Current listing:	Proposed new listing:	PBAC Recommended amendment:	PBAC Recommended new listing:
Max quantity	40	NO CHANGE RECOMMENDED	Nil	NO CHANGE RECOMMENDED
Repeats	1		N/A	
Qty issued with repeat	80		N/A	
Restriction	Authority Required (STREAMLINED) for: <ul style="list-style-type: none"> Osteomyelitis 		N/A	

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Listing 3119E				
Formulation: cefalexin – capsule 500mg (anhydrous)				
	Current listing:	Proposed new listing:	PBAC Recommended amendment:	PBAC Recommended new listing:
Max quantity	20	20	20	40
Repeats	1	1	0	0
Qty issued with repeat	40	40	20	40
Restriction	Unrestricted	Authority Required (STREAMLINED) for: <ul style="list-style-type: none"> • Pin-site infection • Superficial or incisional infection following cardiac implantable electronic device insertion • Acute diffuse otitis externa • Streptococcal pharyngitis and tonsillitis • Lactational mastitis • Periorbital (preseptal) cellulitis • Confirmed acute rheumatic fever • Mild diabetic foot infection • Widespread infection of dermatitis • Prophylaxis regimens for invasive group A streptococcal 	Unrestricted	Authority Required (STREAMLINED) for: <ul style="list-style-type: none"> • Pin-site infection • Infection following cardiac device insertion • Acute otitis externa • Streptococcal pharyngitis or tonsillitis • Mastitis • Periorbital (preseptal) cellulitis • Acute rheumatic fever • Diabetic foot infection • Widespread infection of dermatitis • Prophylaxis for invasive group A streptococcal (iGAS) infection • Impetigo • Pyelonephritis • Conditions where

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		<p>(iGAS) infection</p> <ul style="list-style-type: none"> • Impetigo in non-endemic settings • Nonsevere pyelonephritis in non-pregnant adults • Conditions where prolonged oral antibiotic therapy is required following initial intravenous antibiotic therapy 		<p>prolonged oral antibiotic therapy is required</p>
<p><u>Listing 3058Y</u></p> <p>Formulation: cefalexin – capsule 250mg (anhydrous)</p>				
	Current listing:	Proposed new listing:	PBAC Recommended amendment:	PBAC Recommended new listing:
Max quantity	20	20	20	40
Repeats	1	1	0	0
Qty issued with repeat	40	40	20	40
Restriction	Unrestricted	<p>Authority Required (STREAMLINED) for patients with renal impairment and has one of the following indications:</p> <ul style="list-style-type: none"> • Pin-site infection • Superficial or incisional infection following cardiac implantable electronic device insertion 	Unrestricted	<p>Authority Required (STREAMLINED) for patients with renal impairment and has one of the following indications:</p> <ul style="list-style-type: none"> • Pin-site infection • Infection following cardiac device insertion • Acute otitis externa • Streptococcal

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		<ul style="list-style-type: none"> • Acute diffuse otitis externa • Streptococcal pharyngitis and tonsillitis • Lactational mastitis • Periorbital (preseptal) cellulitis • Confirmed acute rheumatic fever • Mild diabetic foot infection • Widespread infection of dermatitis • Prophylaxis regimens for invasive group A streptococcal (iGAS) infection • Impetigo in non-endemic settings • Nonsevere pyelonephritis in non-pregnant adults • Conditions where prolonged oral antibiotic therapy is required following initial intravenous antibiotic therapy 		<p>pharyngitis or tonsillitis</p> <ul style="list-style-type: none"> • Mastitis • Periorbital (preseptal) cellulitis • Acute rheumatic fever • Diabetic foot infection • Widespread infection of dermatitis • Prophylaxis for invasive group A streptococcal (iGAS) infection • Impetigo • Pyelonephritis • Conditions where prolonged oral antibiotic therapy is required
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Doxycycline				
<u>Listing 02708M</u>				
Formulation: doxycycline - capsule 100mg (as hydrochloride) containing enteric coated pellets				
	Current listing:	Proposed new listing:	PBAC Recommended amendment:	PBAC Recommended new listing:
Max quantity	7 (14 with repeat)	NO CHANGE RECOMMENDED	NO CHANGE RECOMMENDED	NO CHANGE RECOMMENDED
Repeats	1			
Restriction	Unrestricted			
<u>Listing 02709N</u>				
Formulation: doxycycline - tablet 100mg (as hydrochloride)				
	Current listing:	Proposed new listing:	PBAC Recommended amendment:	PBAC Recommended new listing:
Max quantity	7 (14 with repeat)	NO CHANGE RECOMMENDED	NO CHANGE RECOMMENDED	NO CHANGE RECOMMENDED
Repeats	1			
Restriction	Unrestricted			
<u>Listing 09105F</u>				
Formulation: doxycycline - tablet 100mg (as monohydrate)				
	Current listing:	Proposed new listing:	PBAC Recommended amendment:	PBAC Recommended new listing:
Max quantity	7 (14 with repeat)	NO CHANGE RECOMMENDED	NO CHANGE RECOMMENDED	NO CHANGE RECOMMENDED
Repeats	1			
Restriction	Unrestricted			
<u>Listing 02707L</u>				
Formulation: doxycycline - capsule 50mg (as hydrochloride) containing enteric coated pellets				
	Current listing:	Proposed new listing:	PBAC Recommended amendment:	PBAC Recommended new listing:

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Max quantity	25 (125 with repeats)	NO CHANGE RECOMMENDED	NO CHANGE RECOMMENDED	NO CHANGE RECOMMENDED
Repeats	5			
Restriction	Restricted <i>(Bronchiectasis, chronic bronchitis and severe acne patient must be 8 years or older)</i>			
Listing 02711Q:				
Formulation: doxycycline - tablet 50mg (as hydrochloride)				
	Current listing:	Proposed new listing:	PBAC Recommended amendment:	PBAC Recommended new listing:
Max quantity	25 (125 with repeats)	NO CHANGE RECOMMENDED	NO CHANGE RECOMMENDED	NO CHANGE RECOMMENDED
Repeats	5			
Restriction	Restricted <i>(Bronchiectasis, chronic bronchitis and severe acne patient must be 8 years or older)</i>			
Listing 09106G				
Formulation: doxycycline - tablet 50mg (as monohydrate)				
	Current listing:	Proposed new listing:	PBAC Recommended amendment:	PBAC Recommended new listing:
Max quantity	25 (125 with repeats)	NO CHANGE RECOMMENDED	NO CHANGE RECOMMENDED	NO CHANGE RECOMMENDED
Repeats	5			
Restriction	Restricted <i>(Bronchiectasis, chronic bronchitis and severe acne patient must be 8 years or older)</i>			

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<u>Listing 10777F</u>				
Formulation: doxycycline - capsule 100mg (as hydrochloride) containing enteric coated pellets				
	Current listing:	Proposed new listing:	PBAC Recommended amendment:	PBAC Recommended new listing:
Max quantity	28 (140 with repeats)	NO CHANGE RECOMMENDED	NO CHANGE RECOMMENDED	NO CHANGE RECOMMENDED
Repeats	5			
Restriction	Restricted (severe acne)			
<u>Listing 10779H</u>				
Formulation: doxycycline - tablet 100mg (as hydrochloride)				
	Current listing:	Proposed new listing:	PBAC Recommended amendment:	PBAC Recommended new listing:
Max quantity	28 (140 with repeats)	NO CHANGE RECOMMENDED	NO CHANGE RECOMMENDED	NO CHANGE RECOMMENDED
Repeats	5			
Restriction	Restricted (severe acne)			
<u>Listing 10781K</u>				
Formulation: doxycycline - tablet 100mg (as monohydrate)				
	Current listing:	Proposed new listing:	PBAC Recommended amendment:	PBAC Recommended new listing:
Max quantity	28 (140 with repeats)	NO CHANGE RECOMMENDED	NO CHANGE RECOMMENDED	NO CHANGE RECOMMENDED
Repeats	5			
Restriction	Restricted (severe acne)			
<i>Roxithromycin</i>				
<u>Listing 8129W</u>				
Formulation: roxithromycin – tablet 50mg				
	Current listing:	Proposed new listing:	PBAC Recommended amendment:	PBAC Recommended new listing:

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Max quantity	10	10	10	Nil
Repeats	1	0	0	N/A
Qty issued with repeat	20	10	10	N/A
Restriction	Unrestricted	Unrestricted	Unrestricted	N/A
<u>Listing 1760P</u>				
Formulation: roxithromycin – tablet 150mg				
	Current listing:	Proposed new listing:	PBAC Recommended amendment:	PBAC Recommended new listing:
Max quantity	10	10	10	20
Repeats	1	0	0	0
Qty issued with repeat	20	10	10	20
Restriction	Unrestricted	Unrestricted	Unrestricted	Authority Required (STREAMLINED) for: <ul style="list-style-type: none"> • Conditions where prolonged oral antibiotic therapy is required
<u>Listing 8016X</u>				
Formulation: roxithromycin – tablet 300mg				
	Current listing:	Proposed new listing:	PBAC Recommended amendment:	PBAC Recommended new listing:
Max quantity	5	5	5	20
Repeats	1	0	0	0
Qty issued with repeat	10	5	5	20
Restriction	Unrestricted	Unrestricted	Unrestricted	Authority Required (STREAMLINED) for: <ul style="list-style-type: none"> • Conditions where prolonged oral antibiotic therapy is required

5 Recommended listings

AMOXICILLIN

5.1 No change to the existing listing 8581P:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
AMOXICILLIN amoxicillin 1 g tablet, 14	14	1	Amoxycillin Sandoz Maxamox	Sandoz Pty Ltd Sandoz Pty Ltd

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Midwives
PBS Indication:	Chronic bronchitis
Restriction Level / Method:	<input type="checkbox"/> Unrestricted <input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – Streamlined
Clinical criteria:	Patient must have acute exacerbations of the condition.

5.2 Amend existing listing 1884E as follows:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
AMOXICILLIN amoxicillin 250 mg capsule, 20	20	4 0	AMILOXYN APO-Amoxycillin Alphamox 250 Amoxycillin AN Amoxycillin Ranbaxy Amoxycillin Sandoz Cilamox Amoxil	Arrow Pharma Pty Ltd Apotex Pty Ltd Alphapharm Pty Ltd Amneal Pharmaceuticals Pty Ltd Sun Pharma ANZ Pty Ltd Sandoz Pty Ltd Alphapharm Pty Ltd Aspen Pharma Pty Ltd

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input checked="" type="checkbox"/> Midwives
Restriction Level / Method:	<input checked="" type="checkbox"/> Unrestricted <input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – Streamlined
Administrative Advice:	<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>

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5.3 Amend existing listing 1889K as follows:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
AMOXICILLIN amoxicillin 500 mg capsule, 20	20	4 0	AMILOXYN APO-Amoxycillin Alphamox 500 Amoxycillin AN Amoxycillin Ranbaxy Amoxycillin Sandoz Amoxycillin generichealth 500 Cilamox Amoxil	Arrow Pharma Pty Ltd Apotex Pty Ltd Alphapharm Pty Ltd Amneal Pharmaceuticals Pty Ltd Sun Pharma ANZ Pty Ltd Sandoz Pty Ltd Generic Health Pty Ltd Alphapharm Pty Ltd Aspen Pharma Pty Ltd

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input checked="" type="checkbox"/> Midwives
Restriction Level / Method:	<input checked="" type="checkbox"/> Unrestricted <input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – Streamlined
Administrative Advice:	<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>

5.4 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
AMOXICILLIN amoxicillin 500 mg capsule, 20	40	0	AMILOXYN APO-Amoxycillin Alphamox 250 Amoxycillin AN Amoxycillin Ranbaxy Amoxycillin Sandoz Cilamox Amoxil	Arrow Pharma Pty Ltd Apotex Pty Ltd Alphapharm Pty Ltd Amneal Pharmaceuticals Pty Ltd Sun Pharma ANZ Pty Ltd Sandoz Pty Ltd Generic Health Pty Ltd Aspen Pharma Pty Ltd

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
Restriction Level / Method:	<input type="checkbox"/> Unrestricted <input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required – Streamlined
Clinical criteria:	Patient must be a male with acute cystitis OR Patient must have pyelonephritis OR Patient must have a tooth avulsion OR Patient must have Salmonella enteritis OR Patient must have a condition requiring prolonged oral antibiotic therapy.

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AMOXICILLIN & CLAVULANIC ACID

5.5 Amend existing listing 1891M as follows:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
AMOXICILLIN + CLAVULANIC ACID			AMCLAVOX DUO	Arrow Pharma Pty Ltd
amoxicillin 500 mg + clavulanic acid 125 mg	10	4 0	500/125	
tablet, 10			AMOXICLAV AMNEAL	Amneal Pharmaceuticals Pty Ltd
			500/125	
			APO-Amoxycillin/ Clavulanic Acid 500/125	Apotex Pty Ltd
			AlphaClav Duo	Alphapharm Pty Ltd
			Amoxyclav AN 500/125	Amneal Pharmaceuticals Pty Ltd
			Curam Duo 500/125	Sandoz Pty Ltd
			Moxiclav Duo 500/125	Aspen Pharma Pty Ltd
			Augmentin Duo	Aspen Pharmacare Australia Pty Limited

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input checked="" type="checkbox"/> Midwives
PBS Indication:	Infection where resistance to amoxicillin is suspected, and Infection where resistance to amoxicillin is proven.
Restriction Level / Method:	<input type="checkbox"/> Unrestricted <input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – Streamlined
Cautions:	Hepatotoxicity has been reported with this drug.
Administrative Advice:	<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>

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5.6 Amend existing listing 8254K as follows:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
AMOXICILLIN + CLAVULANIC ACID amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10	10	4 0	AMCLAVOX DUO	Arrow Pharma Pty Ltd
			FORTE 875/125	
			AMOXICLAV AMNEAL	Amneal Pharmaceuticals Pty Ltd
			875/125	
			APO-Amoxycillin and Clavulanic Acid	Apotex Pty Ltd
			AlphaClav Duo Forte	Alphapharm Pty Ltd
			AmoxyClav	Generic Health Pty Ltd
			generichealth 875/125	
			Amoxyclav AN 875/125	Amneal Pharmaceuticals Pty Ltd
			Clavam 875 mg/125 mg	Pharmacor Pty Limited
Curam Duo Forte	Sandoz Pty Ltd			
875/125				
Moxiclav Duo Forte	Aspen Pharma Pty Ltd			
875/125				
Augmentin Duo forte	Aspen Pharmacare Australia Pty Limited			

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
PBS Indication:	Infection where resistance to amoxicillin is suspected; and Infection where resistance to amoxicillin is proven.
Restriction Level / Method:	<input type="checkbox"/> Unrestricted <input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – Streamlined
Cautions:	Hepatotoxicity has been reported with this drug.
Administrative Advice:	<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>

5.7 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
AMOXICILLIN + CLAVULANIC ACID amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10	20	0	AMCLAVOX DUO	Arrow Pharma Pty Ltd
			500/125	
			AMOXICLAV AMNEAL	Amneal Pharmaceuticals Pty Ltd
			500/125	
			APO-Amoxycillin/ Clavulanic Acid 500/125	Apotex Pty Ltd
			AlphaClav Duo	Alphapharm Pty Ltd
			Amoxyclav AN 500/125	Amneal Pharmaceuticals Pty Ltd
			Curam Duo 500/125	Sandoz Pty Ltd
			Moxiclav Duo 500/125	Aspen Pharma Pty Ltd
			Augmentin Duo	Aspen Pharmacare Australia Pty Limited

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners

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PBS Indication:	Infection
Restriction Level / Method:	<input type="checkbox"/> Unrestricted <input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required – Streamlined
Clinical criteria:	Patient must be a male with acute cystitis OR Patient must have a condition requiring prolonged oral antibiotic therapy

5.8 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
AMOXICILLIN + CLAVULANIC ACID amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10	20	0	AMCLAVOX DUO FORTE 875/125	Arrow Pharma Pty Ltd
			AMOXICLAV AMNEAL 875/125	Amneal Pharmaceuticals Pty Ltd
			APO-Amoxycillin and Clavulanic Acid	Apotex Pty Ltd
			AlphaClav Duo Forte	Alphapharm Pty Ltd
			AmoxyClav generichealth 875/125	Generic Health Pty Ltd
			Amoxyclav AN 875/125	Amneal Pharmaceuticals Pty Ltd
			Clavam 875 mg/125 mg	Pharmacor Pty Limited
			Curam Duo Forte 875/125	Sandoz Pty Ltd
			Moxiclav Duo Forte 875/125	Aspen Pharma Pty Ltd
			Augmentin Duo forte	Aspen Pharmacare Australia Pty Limited

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input checked="" type="checkbox"/> Midwives
Restriction Level / Method:	<input type="checkbox"/> Unrestricted <input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required – Streamlined
Clinical criteria:	Patient must have periorbital (preseptal) cellulitis OR Patient must have postpartum endometritis OR Patient must have an exacerbation of bronchiectasis OR Patient must have pyelonephritis OR Patient must have pneumonia acquired in hospital or aged care OR Patient must have a diabetic foot infection OR Patient must have a condition requiring prolonged oral antibiotic therapy

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CEFALEXIN

5.9 No change to the existing listing 2655R:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
CEFALEXIN cefalexin 250 mg capsule, 20	40	2	APO-Cephalexin Cefalexin Sandoz Cephalexin AN Ibilex 250 Keflex	Apotex Pty Ltd Sandoz Pty Ltd Amneal Pharmaceuticals Pty Ltd Alphapharm Pty Ltd Aspen Pharmacare Australia Pty Limited

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners
PBS Indication:	Prophylaxis of urinary tract infection
Restriction Level / Method:	<input type="checkbox"/> Unrestricted <input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required – Streamlined

5.10 No change to the existing listing 10778G:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
CEFALEXIN cefalexin 500 mg capsule, 20	40	1	APO-Cephalexin Cefalexin Sandoz Cephalex 500 Cephalexin AN Cephalexin generichealth Ibilex 500 Keflex	Apotex Pty Ltd Sandoz Pty Ltd Pharmacor Pty Limited Amneal Pharmaceuticals Pty Ltd Generic Health Pty Ltd Alphapharm Pty Ltd Aspen Pharmacare Australia Pty Limited

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners
PBS Indication:	Osteomyelitis
Restriction Level / Method:	<input type="checkbox"/> Unrestricted <input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required – Streamlined

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5.11 Amend existing listing 3058Y as follows:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
CEFALEXIN cefalexin 250 mg capsule, 20	20	4 0	APO-Cephalexin Cefalexin Sandoz Cephalexin AN Ibilex 250 Keflex	Apotex Pty Ltd Sandoz Pty Ltd Amneal Pharmaceuticals Pty Ltd Alphapharm Pty Ltd Aspen Pharmacare Australia Pty Limited

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input checked="" type="checkbox"/> Midwives
Restriction Level / Method:	<input checked="" type="checkbox"/> Unrestricted <input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – Streamlined
Administrative Advice:	<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>

5.12 Amend existing listing 3119E as follows:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
CEFALEXIN cefalexin 500 mg capsule, 20	20	4 0	APO-Cephalexin Cefalexin Sandoz Cephalex 500 Cephalexin AN Cephalexin generichealth Ibilex 500 Keflex	Apotex Pty Ltd Sandoz Pty Ltd Pharmacor Pty Limited Amneal Pharmaceuticals Pty Ltd Generic Health Pty Ltd Alphapharm Pty Ltd Aspen Pharmacare Australia Pty Limited

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input checked="" type="checkbox"/> Midwives
Restriction Level / Method:	<input checked="" type="checkbox"/> Unrestricted <input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – Streamlined
Administrative Advice:	<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>

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5.13 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
CEFALEXIN cefalexin 250 mg capsule, 20	40	0	APO-Cephalexin Cefalexin Sandoz Cephalexin AN Ibilex 250 Keflex	Apotex Pty Ltd Sandoz Pty Ltd Amneal Pharmaceuticals Pty Ltd Alphapharm Pty Ltd Aspen Pharmacare Australia Pty Limited

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input checked="" type="checkbox"/> Midwives
Restriction Level / Method:	<input type="checkbox"/> Unrestricted <input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required – Streamlined
Clinical criteria:	Patient must have impaired renal function AND Patient must have a pin-site infection OR Patient must have an infection following cardiac device insertion OR Patient must have acute otitis externa OR Patient must have streptococcal pharyngitis or tonsillitis OR Patient must have mastitis OR Patient must have periorbital (preseptal) cellulitis OR Patient must have acute rheumatic fever OR Patient must have a diabetic foot infection OR Patient must have a widespread infection of dermatitis OR Patient must require treatment for prophylaxis for invasive group A streptococcal (iGAS) infection OR Patient must have impetigo OR Patient must have pyelonephritis OR Patient must have a condition where prolonged oral antibiotic therapy is required.

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5.14 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
CEFALEXIN cefalexin 500 mg capsule, 20	40	0	APO-Cephalexin Cefalexin Sandoz Cephalex 500 Cephalexin AN Cephalexin generichealth Ibilex 500 Keflex	Apotex Pty Ltd Sandoz Pty Ltd Pharmacor Pty Limited Amneal Pharmaceuticals Pty Ltd Generic Health Pty Ltd Alphapharm Pty Ltd Aspen Pharmacare Australia Pty Limited

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input checked="" type="checkbox"/> Midwives
Restriction Level / Method:	<input type="checkbox"/> Unrestricted <input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required – Streamlined
Clinical criteria:	Patient must have a pin-site infection OR Patient must have an infection following cardiac device insertion OR Patient must have acute otitis externa OR Patient must have streptococcal pharyngitis or tonsillitis OR Patient must have mastitis OR Patient must have periorbital (preseptal) cellulitis OR Patient must have acute rheumatic fever OR Patient must have a diabetic foot infection OR Patient must have a widespread infection of dermatitis OR Patient must require treatment for prophylaxis for invasive group A streptococcal (iGAS) infection OR Patient must have impetigo OR Patient must have pyelonephritis OR Patient must have a condition where prolonged oral antibiotic therapy is required.

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DOXYCYCLINE

- 5.15 No change to the existing listings for doxycycline 50 mg tablet: 2711Q and 9106G.
- 5.16 No change to the existing listing for doxycycline 50 mg modified release capsule: 2707L.
- 5.17 No change to the existing listings for doxycycline 100 mg tablet: 10779H, 10781K, 2709N, 9105F.
- 5.18 No change to the existing listings for doxycycline 100 mg modified release capsule: 10777F, 2708M.

ROXITHROMYCIN

- 5.19 Amend existing listing 8129W as follows:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
ROXITHROMYCIN roxithromycin 50 mg dispersible tablet, 10	10	4 0	Rulide D	Sanofi-Aventis Australia Pty Ltd

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Midwives
Restriction Level / Method:	<input checked="" type="checkbox"/> Unrestricted <input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – Streamlined
Administrative Advice:	<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>

- 5.20 Amend existing listing 1760P as follows:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
ROXITHROMYCIN roxithromycin 150 mg tablet, 10	10	4 0	APO-Roxithromycin Biaxsig	Apotex Pty Ltd Sanofi-Aventis Australia Pty Ltd
			Chem mart Roxithromycin	Apotex Pty Ltd
			Roxar 150 Roximycin	Arrow Pharma Pty Ltd Alphapharm Pty Ltd
			Roxithromycin AN	Amneal Pharmaceuticals Pty Ltd
			Roxithromycin Sandoz Roxithromycin-GA	Sandoz Pty Ltd Amneal Pharmaceuticals Pty Ltd
			Terry White Chemists Roxithromycin	Apotex Pty Ltd
			Rulide	Sanofi-Aventis Australia Pty Ltd

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Midwives

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Restriction Level / Method:	<input checked="" type="checkbox"/> Unrestricted <input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – Streamlined
Administrative Advice:	<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>

5.21 Amend existing listing 8016X as follows:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
ROXITHROMYCIN	5	40	APO-Roxithromycin	Apotex Pty Ltd
roxithromycin 300 mg tablet, 5			Biaxsig	Sanofi-Aventis Australia Pty Ltd
			Chem mart	Apotex Pty Ltd
			Roxithromycin	
			Roxar 300	Arrow Pharma Pty Ltd
			Roximycin	Alphapharm Pty Ltd
			Roxithromycin AN	Amneal Pharmaceuticals Pty Ltd
			Roxithromycin Sandoz	Sandoz Pty Ltd
			Roxithromycin-GA	Amneal Pharmaceuticals Pty Ltd
			Terry White Chemists	Apotex Pty Ltd
	Roxithromycin			
	Rulide	Sanofi-Aventis Australia Pty Ltd		

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Midwives
Restriction Level / Method:	<input checked="" type="checkbox"/> Unrestricted <input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – Streamlined
Administrative Advice:	<i>No applications for increased maximum quantities and/or repeats will be authorised.</i>

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5.22 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
AMOXICILLIN amoxicillin 1 g tablet, 14	14	1	Amoxycillin Sandoz Maxamox	Sandoz Pty Ltd Sandoz Pty Ltd

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Midwives
PBS Indication:	Community acquired pneumonia
Restriction Level / Method:	<input type="checkbox"/> Unrestricted <input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required – Streamlined
Clinical criteria:	Patient must have community acquired pneumonia.

5.23 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
AMOXICILLIN amoxicillin 250 mg capsule, 20	40	0	AMILOXYN APO-Amoxycillin Alphamox 250 Amoxycillin AN	Arrow Pharma Pty Ltd Apotex Pty Ltd Alphapharm Pty Ltd Amneal Pharmaceuticals Pty Ltd
			Amoxycillin Ranbaxy Amoxycillin Sandoz Cilamox Amoxil	Sun Pharma ANZ Pty Ltd Sandoz Pty Ltd Alphapharm Pty Ltd Aspen Pharma Pty Ltd

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Midwives
PBS Indication:	Infection
Restriction Level / Method:	<input type="checkbox"/> Unrestricted <input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required – Streamlined
Clinical criteria:	Patient must have a condition requiring prolonged oral antibiotic therapy.

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5.24 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
ROXITHROMYCIN roxithromycin 150 mg tablet, 10	20	0	APO-Roxithromycin Biaxsig Chem mart Roxithromycin Roxar 150 Roximycin Roxithromycin AN Roxithromycin Sandoz Roxithromycin-GA Terry White Chemists Roxithromycin Rulide	Apotex Pty Ltd Sanofi-Aventis Australia Pty Ltd Apotex Pty Ltd Arrow Pharma Pty Ltd Alphapharm Pty Ltd Amneal Pharmaceuticals Pty Ltd Sandoz Pty Ltd Amneal Pharmaceuticals Pty Ltd Apotex Pty Ltd Sanofi-Aventis Australia Pty Ltd

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Midwives
PBS Indication:	Infection
Restriction Level / Method:	<input type="checkbox"/> Unrestricted <input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required – Streamlined
Clinical criteria:	Patient must have a condition requiring prolonged oral antibiotic therapy.

5.25 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
ROXITHROMYCIN roxithromycin 300 mg tablet, 5	10	0	APO-Roxithromycin Biaxsig Chem mart Roxithromycin Roxar 300 Roximycin Roxithromycin AN Roxithromycin Sandoz Roxithromycin-GA Terry White Chemists Roxithromycin Rulide	Apotex Pty Ltd Sanofi-Aventis Australia Pty Ltd Apotex Pty Ltd Arrow Pharma Pty Ltd Alphapharm Pty Ltd Amneal Pharmaceuticals Pty Ltd Sandoz Pty Ltd Amneal Pharmaceuticals Pty Ltd Apotex Pty Ltd Sanofi-Aventis Australia Pty Ltd

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Midwives

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PBS Indication:	Infection
Restriction Level / Method:	<input type="checkbox"/> Unrestricted <input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required – Streamlined
Clinical criteria:	Patient must have a condition requiring prolonged oral antibiotic therapy.

6 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.