

Recommendations made by the PBAC – September 2024 intracycle meeting

Last updated: 1 November 2024

Endorsed midwife – PBS listings

At its <u>September 2024 intracycle meeting</u>, the Pharmaceutical Benefits Advisory Committee (PBAC) considered approximately 50 medicines listed on the Pharmaceutical Benefits Scheme (PBS) identified through consultation that were requested for prescribing by endorsed midwives. The PBAC made its recommendations with reference to its general principles for determining PBS prescriber eligibility. The PBAC's recommendations and rationale from the guidance principles are summarised in tables below.

The PBAC recommended that PBS listings for over 30 medicines be amended to allow PBS prescribing by endorsed midwives without any further conditions beyond those that may already specified in PBS restrictions (Table 1). The PBAC considered that the midwifery/ obstetric proposed uses are likely to be covered by the existing PBS listings, but reiterated that endorsed midwives should ensure that prescribing is in accordance with any PBS restrictions where specified. For an additional 11 medicines (Table 2), the PBAC recommended that endorsed midwives be added as authorised prescribers under certain circumstances (e.g. for continuing therapy only, where care of the patient is shared with a medical practitioner). The PBAC recommended that endorsed midwives be added as authorised prescribers during the prescribers for several Prescriber Bag listings (included in Table 1). The PBAC noted that some medicines requested by stakeholders for inclusion in the Prescriber Bag for endorsed midwives are not currently PBS-listed and would require a submission from a sponsor.

The PBAC did not recommend the addition of endorsed midwives as authorised prescribers for some medicines (Table 3) due to the following reasons: where the proposed use is not Therapeutic Goods Administration (TGA) registered; the medicine is currently withdrawn from the market; or clinical guidelines do not support use of the medicine during pregnancy in favour of alternative medicines. Some requested medicines (Table 4) were excluded from PBAC consideration if they were not already listed on the PBS, or the intended form, presentation or indication were not PBS-listed.

Implementation

The PBAC's recommendations are expected to be implemented in the first half of 2025 as part of routine monthly changes to the PBS schedule. PBS prescribers should check the schedule regularly to ensure they prescribe in accordance with any restrictions specified in a listing.

More information can be found by visiting 'Review of PBS items for prescribing by nurse practitioners and endorsed midwives' on the PBS website (<u>www.pbs.gov.au</u>).



Table 1: Medicines recommended by the PBAC for PBS prescribing by an endorsed midwife

Medicine	Relevant PBS restriction	Midwifery/obstetric purpose cited
Anti-infectives		
Aciclovir	Initial or recurrent moderate to severe genital herpes – episodic	Prevention of herpes outbreak from 36 weeks or treatment of existing
Valaciclovir	or suppressive therapy	outbreak
Amoxicillin + Clavulanic acid	Infection where resistance to amoxicillin is suspected or proven	Post-natal perineal infection
Amoxicillin liquid	Unrestricted benefit	As an alternative dose form to solid oral dose forms in patients having difficulty swallowing a solid oral dose form
Azithromycin	Urethritis or cervicitis due to chlamydia trachomatis	Sexually transmitted infection
Benzylpenicillin 3 g injection	Prescriber bag listing	First line management of suspected sepsis in labour, Group B streptococcus positivity in labour
Cefalexin liquid	Unrestricted benefit	Mastitis - as an alternative dose form to solid oral dose forms in patients having difficulty swallowing a solid oral dose form
Cefazolin	Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent	Group B streptococcus positivity in labour Mastitis
Ceftriaxone	Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent	Sexually transmitted infection
Doxycycline	Unrestricted benefit	Sexually transmitted infection
Erythromycin	Unrestricted benefit	Prolonged rupture of membranes
Flucloxacillin injection, oral liquid	Unrestricted benefit, Serious staphylococcal infection	Mastitis
Metronidazole oral liquid, tablets	Unrestricted benefit, Anaerobic infections	Bacterial vaginosis
Trimethoprim	Unrestricted benefit	Urinary tract infection
Vancomycin injection	Infection where treatment is initiated in a hospital	Group B streptococcus positivity in labour
Contraceptives		
Norethisterone 350 mcg tablets	Unrestricted benefit	Contraception in breastfeeding mothers
Medroxyprogesterone depot injection	Unrestricted benefit	Contraception
Levonorgestrel 19.5 mg IUD (Kyleena)	Contraception	Contraception



Medicine	Relevant PBS restriction	Midwifery/obstetric purpose cited	
Levonorgestrel 52 mg IUD (Mirena)			
Pain relief			
Diclofenac tablets	Unrestricted benefit	Pain and inflammation	
Indometacin suppositories	Unrestricted benefit	Pain and inflammation	
Paracetamol + codeine	Short term acute severe pain	Analgesia	
Lidocaine 1% injection	Prescriber bag listing	Local anaesthetic	
Iron deficiency			
Iron (as ferric carboxymaltose) Iron (as polymaltose)	Unrestricted benefit	Iron deficient anaemia in pregnancy Treatment of low iron postnatally following postpartum haemorrhage	
Ferrous fumarate (including in combination with folic acid)	For treatment of a patient identifying as Aboriginal or Torres Strait Islander	Iron deficiency in someone identifying as Aboriginal or Torres Strait Islander who is pregnant	
Stomach acid suppression			
Omeprazole Esomeprazole 20 mg	Initial treatment or short-term maintenance treatment of gastro-oesophageal reflux	GORD	
Anti-emesis	disorder (GORD)		
Prochlorperazine	Unrestricted benefit (General schedule) Prescriber bag listings	Antiemetic	
Promethazine	Unrestricted benefit (General schedule) Prescriber bag listings	Antiemetic	
Lactation related			
Cabergoline	Prevention of the onset of lactation in the puerperium for medical reasons	Suppression of lactation following stillbirth or neonatal death	
Miscellaneous			
Naloxone	Unrestricted benefit (General schedule) Prescriber bag listings	Opioid overdose	
Folic acid	For treatment of a patient identifying as Aboriginal or Torres Strait Islander	Folate deficiency in a pregnant patient identifying as Aboriginal or Torres Strait Islander	



Department of Health and Aged Care

Table 2: Medicines recommended by the PBAC for PBS prescribing by an endorsed midwife under certain circumstances

Medicine - purpose	Relevant PBS restriction	Circumstances and rationale
Analgesia		
Oxycodone 5 mg capsules, tablets, 10 units – acute post-operative pain	Severe pain – acute, short term, where non-opioids are inadequate.	Principle 3 – Medicine specific considerations Treatment must be shared with a medical practitioner to limit prescribing to the proposed purpose only (i.e. severe post-partum pain following surgery) and ensure there are not underlying medical concerns.
Tramadol 50 mg immediate release capsules – acute post-operative pain	Severe pain – acute, short term, where non-opioids are inadequate.	As above for oxycodone
Anti-infectives		
Benzylpenicillin 3 g - first line management of suspected	Unrestricted benefit (General schedule)	Principle 4 - Health condition specific considerations
sepsis in labour, GBS positivity in labour		Add a Caution note that patient care be shared with a medical practitioner when prescribed by a non-medical practitioner for suspected sepsis as a matter of urgency. The severity of the proposed use warrants medical practitioner involvement as prompt rapid escalation may be required.
Gentamicin – first line management of suspected sepsis in labour	Unrestricted benefit	As above for benzylpenicillin
Anti-hypertensives		
Labetalol - hypertension	Unrestricted benefit	Principle 4 - Health condition specific considerations
		Continuing therapy only after initiation by a medical practitioner in the current pregnancy; treatment for this condition must be shared with a medical practitioner. To assist in ensuring the underlying causes(s) of the hypertension are investigated and treated appropriately before the commencement of drug therapy.
Methyldopa - hypertension	Hypertension in a pregnant patient	As above for labetalol.
Miscellaneous	1	1
Enoxaparin – thromboprophylaxis	Unrestricted benefit	Principle 4 - Health condition specific considerations



Medicine - purpose	Relevant PBS restriction	Circumstances and rationale
		Continuing therapy only; initiation by a medical practitioner for the current pregnancy/post- partum episode. Treatment must be shared with a medical practitioner to address the marked increased risk of thromboembolism in pregnancy/the post-partum period compared to that in a non-pregnant woman.
Hydroxocobalamin – vitamin B12 deficiency	Pernicious anaemia or proven vitamin B12 deficiencies other than pernicious anaemia in a patient identifying as Aboriginal or Torres Strait Islander.	Principle 4 - Health condition specific considerations Treatment must be shared with a medical practitioner to assist in ensuring that the underlying cause(s) of anaemia are investigated and treated appropriately.
Levothyroxine - hypothyroidism	Unrestricted benefit	Principle 4 - Health condition specific considerations Continuing therapy only. Treatment must be shared with a medical practitioner to assist in ensuring the underlying causes of hypothyroidism are investigated and treated appropriately before the commencement of drug therapy.
Metformin - diabetes	Unrestricted benefit	Principle 4 - Health condition specific considerations Continuing therapy only. Treatment must be shared with a medical practitioner to assist in ensuring the underlying causes of diabetes are investigated and treated appropriately before the commencement of drug therapy.
Temazepam – insomnia	Unrestricted benefit	Principle 3 - Medicine specific considerations Treatment must be shared with a medical practitioner to assist in ensuring the underlying causes(s) are investigated and treated appropriately, as well to ensure short term use only.

Table 3: Medicines not recommended by the PBAC for PBS prescribing by an endorsed midwife

Medicine	Reason
Domperidone	The proposed use (increase lactation post-partum) is not a TGA registered indication
Terbutaline injection	The proposed use (tocolytic) is not a TGA registered indication
Ondansetron	The proposed use (nausea/vomiting associated with pregnancy) is not a TGA registered indication
Ranitidine 300 mg	Medicine is currently withdrawn from the market



Medicine	Reason
Enalapril	Clinical guidelines do not support use of the medicine during pregnancy in favour of alternative medicines
Pantoprazole	Clinical guidelines do not support use of the medicine during pregnancy in favour of alternative medicines

Table 4: Medicines excluded from consideration for PBS prescribing by an endorsed midwife due to not being PBS-listed

Medication	Midwifery/obstetric indication
Chloramphenicol ointment	Infection
Clindamycin vaginal cream, injection	Bacterial vaginosis
Clotrimazole cream	Fungal infection
Combined oral contraceptive pills x 8	Contraception
Copper IUD	Contraception
Etonogestrel with ethinylestradiol vaginal ring	Contraception
Ergometrine	Uterotonic Management of third stage of labour and post-partum haemorrhage
Fluconazole single tablet (Pharmacist only medicine (Schedule 3))	Thrush
Levonorgestrel single tablet (Schedule 3)	Emergency contraception
Lignocaine with adrenaline	Local anaesthetic
Magnesium sulphate injection	Anti-convulsant
Metronidazole injection	First line management of suspected sepsis in labour
Miconazole oral gel (Schedule 3)	Fungal infections of the nipple/breast
Mifepristone as the single drug	Pregnancy termination
Misoprostol as the single drug	Management of third stage of labour and post-partum haemorrhage
Mupirocin ointment	Skin infection (ointment is RPBS listed for skin infection; PBS listing is for nasal infection)
Nifedipine immediate release tablets	Anti-hypertensive
Nitrous oxide	Analgesia
Nystatin vaginal cream, oral liquid	Vaginal thrush, nipple thrush
Oseltamivir	Viral infection
Oxytocin	Anti-haemorrhagic Management of third stage of labour Post-partum haemorrhage
Oxytocin with ergometrine	Management of third stage of labour Post-partum haemorrhage
Phytomenadione paediatric formulation	Prevention of haemolytic disease of the foetus and newborn
Promethazine liquid, tablets (Schedule 3)	Anti-emetic
Prostaglandin E2	Cervical ripening
Duridenia (diterria DO)	Unstated
Pyridoxine (vitamin B6)	Unstated