

Pharmaceutical Benefits Scheme (PBS) Listings

1 September 2026

Please find below information relating to new and amended Pharmaceutical Benefits Scheme (PBS) listings implemented on **1 September 2026**.

This information relates to the administration of these listings by Services Australia. For further information on broader PBS changes, please visit the PBS website. Relevant information and authority application forms have been updated and can be accessed through the Services Australia website.

Uncontrolled chronic obstructive pulmonary disease (COPD)

Mepolizumab (100 mg/mL injection, 1 mL pen device) (Nucala®) is now listed on the PBS for the treatment of uncontrolled COPD. Authority applications for initial and grandfather treatments can be made using the Online PBS Authorities system or in writing. Authority applications for continuing treatment can be made using the Online PBS Authorities system or by telephone.

Resected gastric and gastroesophageal junction adenocarcinoma

Durvalumab (120 mg/2.4 mL injection, 2.4 mL vial; 500 mg/10 mL injection, 10 mL vial) (Imfinzi®) is now listed on the PBS for the neoadjuvant treatment of resectable gastric and gastroesophageal junction adenocarcinoma and for the adjuvant treatment of resected gastric and gastroesophageal junction adenocarcinoma. Authority applications for adjuvant and neoadjuvant treatments can be made using the Online PBS Authorities system or by telephone.

Hormone sensitive carcinoma of the prostate

Enzalutamide (40 mg capsule, 112) (Xtandi®) is now listed on the PBS for the treatment of hormone sensitive carcinoma of the prostate. Authority applications for treatment can be made using the Online PBS Authorities system or by telephone.

Lupus nephritis

Obinutuzumab (1 g/40 mL injection, 40 mL vial) (Gazyva®) is now listed on the PBS for the treatment of lupus nephritis. Authority applications for initial, first continuing and subsequent continuing treatment can be made using the Online PBS Authorities system or by telephone.

Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer

Enfortumab vedotin (20 mg injection, 1 vial; 30 mg injection, 1 vial) (Padcev®) is now listed on the PBS to be used in combination with pembrolizumab (100 mg/4 mL injection, 4 mL vial) (Keytruda®), for the first line treatment of locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer. Prescriptions for treatment are Authority Required (STREAMLINED).

Immunotherapy sensitive advanced or metastatic cancer

Pembrolizumab (100 mg/4 mL injection, 4 mL vial) (Keytruda®) is now listed on the PBS for the treatment of immunotherapy sensitive advanced or metastatic cancer. A number of indications have been consolidated into the new listings. As a result, a number of item codes have been

deleted, and new prescriptions will be needed from 1 September 2026. Prescriptions for treatments are Authority required (STREAMLINED).

Bacterial infections

Azithromycin (500 mg tablet, 2) (APO-Azithromycin®, Azithromycin Sandoz®, Azithromycin Viatris®, AZITHROMYCIN-WGR®, ZITHRO®, Zithromax®); (200 mg/5 mL powder for oral liquid, 15 mL) (Zithromax®) has had a change of authority level from Restricted benefit to now being listed as an Unrestricted benefit. For azithromycin tablets, there has also been a change to the maximum quantity and number of repeats.

Dermatitis herpetiformis; Leprosy

Dapsone (25 mg tablet, 100) (Dapsone Tablets®, USP 25 mg (Rising Pharmaceuticals, USA)®) is now listed on the PBS for the current supply shortage under Section 19A. It is listed as an Unrestricted benefit.

Ventricular arrhythmias

Disopyramide (100 mg capsule, 100) (Rythmodan (Japan)®) is now listed on the PBS for the current supply shortage under Section 19A. It is listed as a Restricted benefit.

Menopausal hormone therapy

Estradiol (25 microgram/24 hours patch, 8; 50 microgram/24 hours patch, 8) (Dermestril 25 (Italy)®) (Dermestril 50 (Italy)®) is now listed on the PBS for the current supply shortage under Section 19A. It is listed as an Unrestricted benefit.

Infections

Benzathine benzylpenicillin (1.2 million units powder for injection [1 vial] (& inert substance diluent [4 mL ampoule], 1 pack) (Benzetacil (Spain)®) is now listed on the PBS for the current supply shortage under Section 19A. It is listed as an Unrestricted benefit.

Malignancy

Cyclophosphamide (2 g injection, 1 vial) (Cyclophosphamide (Sagent, USA)®) is now listed on the PBS for the current supply shortage under Section 19A. It is listed as Unrestricted benefit.

1 September 2026 delisted PBS listings

Paraffin (1 g/g eye ointment, 2 x 3.5 g) (Poly Visc®) has been de-listed with a 6-month supply only period arrangement in place.

IMPORTANT INFORMATION



PBS Authorities – Changes from 1 September 2026 – Complex refractory Fistulising Crohn's disease

Authority applications for initial, change/recommencement and continuing treatment with originator brands can now be made using the Online PBS Authorities system or by telephone. Prescriptions for continuing treatment (biosimilar brands of adalimumab, infliximab IV and ustekinumab SC) and continuing treatment or switching treatment from IV to SC (infliximab SC only) are Authority required (STREAMLINED).



Stronger security coming to PRODA

Services Australia is strengthening PRODA security by introducing **passkeys and authenticator apps** as additional log in options from **10 October 2026**.

Passkeys and authenticator apps provide a more secure, phishing-resistant way to access PRODA, rather than traditional email and password log in methods. Existing log in methods will remain available during the rollout. **PRODA users do not need to do anything at this stage.**

More information and support materials will be available on servicesaustralia.gov.au/proda before the launch.

Please share this information with your staff and clients and look out for further updates as the new security options are introduced.



Integrated clinical and prescribing software

Several clinical and prescribing software developers now have products available for use to request PBS authority approval directly from your clinical and prescribing software. This means you can request PBS authority approval as part of generating the authority prescription rather than calling, applying in writing or self-serving through the PBS Authorities tile in HPOS. For more information, speak with your software provider.



Submitting Pharmaceutical Benefits Scheme (PBS) Written Applications through Health Professional Online Services (HPOS) form upload

When submitting PBS authority forms through HPOS form upload, it is important to select the correct Form Category. For PBS patients, select PBS Authorities. For DVA patients, select RPBS Authorities. Remember that only yourself or your delegate/s are authorised to upload PBS and RPBS Authority applications.

Make sure you've:

- linked your prescriber number to your Provider Digital Access (PRODA) account for HPOS; and
- Set up your delegations in HPOS.

Visit servicesaustralia.gov.au/HPOS for more information on how to Link your Health Identifiers to HPOS and Manage delegations.



PBS Authorities items criteria

Under the PBS, medicines are made available based on recommendations from the Pharmaceutical Benefits Advisory Committee (PBAC). Patients must meet the set criteria to be eligible for PBS subsidised medicines. Services Australia are unable to

provide approval for an Authority Required medication where a patient does not meet the criteria established by PBAC.

If you have concerns or questions about the eligibility criteria set by the PBAC, you can contact the Department of Health, Disability and Ageing by email at pbs@health.gov.au.

REMINDERS



PBS Authorities – written authority application forms

To align with PBS listing changes, forms are updated on the first of the month. Using the most recent form will help avoid delays in obtaining authority approval. Search the Services Australia website to access the most recent forms.



Correct PBS item code

When requesting PBS authorities via the Online PBS Authorities system, ensure you have selected the correct medicine to match what is on the prescription. This will avoid delays with providing patients with the medication they require.



Ensuring you are providing accurate data

It's important to ensure you are providing accurate and up to date information when completing an authority application. Failure to do so may result in your authority request being rejected.



For more information about the Online PBS Authorities system visit www.servicesaustralia.gov.au/hppbsauthorities

Services Australia has a broad range of educational resources on the Health Professional Education Resources website. This includes simulations, podcast and an infographic on the Online PBS Authorities system. Visit <https://hpe.servicesaustralia.gov.au/pharmaceutical-benefits-scheme.html>

Visit servicesaustralia.gov.au/hpwrittenauthoritydrugs on the Services Australia website to find the most up to date authority application form for each drug, program or condition.