# Pharmaceutical Benefits Scheme (PBS) Listings 1 November 2025

Please find below information relating to new and amended Pharmaceutical Benefits Scheme (PBS) listings implemented on **1 November 2025**.

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.

#### Paroxysmal nocturnal haemoglobinuria (PNH)

Iptacopan (200 mg capsule) (Fabhalta®) is now listed on the PBS for the treatment of PNH. Authority applications for initial, grandfather, continuing and returning treatments can be made using the Online PBS Authorities system or in writing.

#### Fibrodysplasia ossificans progressiva (FOP)

Palovarotene (10 mg capsule) (Sohonos®) is now listed on the PBS for flare-up (acute) treatment of FOP. Authority applications for chronic treatment of FOP can be made using the Online PBS Authorities system or in writing. Prescriptions for flare-up (acute) treatment are Authority required (STREAMLINED).

#### Stage III or IV CD30 positive Hodgkin lymphoma

Brentuximab vedotin (50 mg injection, 1 vial) (Adcetris®) is now listed on the PBS for the treatment of stage III or IV CD30 positive Hodgkin lymphoma. Authority applications for treatment can be made using the Online PBS Authorities system or by telephone.

#### Untreated multiple myeloma

Daratumumab (100 mg/5 mL injection, 5 mL vial; 400 mg/20 mL injection, 20 mL vial) (Darzalex®); (1.8 g/15 mL injection,15 mL vial) (Darzalex SC®) is now listed on the PBS for the treatment of untreated multiple myeloma. Authority applications for initial, grandfather and continuing treatments can be made using the Online PBS Authorities system or by telephone.

#### Primary biliary cholangitis (previously known as Primary biliary cirrhosis)

Elafibranor (80 mg tablet) (Iqirvo®) is now listed on the PBS for the treatment of primary biliary cholangitis (previously known as Primary biliary cirrhosis). Authority applications for initial and grandfather treatments can be made using the Online PBS Authorities system or by telephone. Prescriptions for continuing treatment are Authority required (STREAMLINED).

#### Schizophrenia

Brexpiprazole (500 microgram tablet) (Rexulti®) is now listed on the PBS for treatment of schizophrenia. Prescriptions for treatment are Authority required (STREAMLINED).

### Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Durvalumab (120 mg/2.4 mL injection, 2.4 mL vial; 500 mg/10 mL injection, 10 mL vial) (Imfinzi®) and tremelimumab (300 mg/15 mL injection, 15 mL vial) (Imjudo®) are now listed on the PBS for the treatment of advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma. Authority applications for initial and continuing treatment with durvalumab are Authority required (STREAMLINED). Prescriptions for initial treatment with tremelimumab are Authority required (STREAMLINED).

#### Chronic kidney disease

Empagliflozin (10 mg tablet) (Jardiance®) has had a change to the restriction for the treatment of chronic kidney disease. Prescriptions for treatment are Authority required (STREAMLINED).

## Severe active rheumatoid arthritis; ankylosing spondylitis; severe psoriatic arthritis; severe chronic plaque psoriasis; severe Crohn's disease; complex refractory fistulising Crohn's disease; moderate to severe ulcerative colitis

Infliximab (100 mg injection, 1 vial) (Ixifi®; Remsima®) has 2 new biosimilars now listed on the PBS for the treatment of severe active rheumatoid arthritis, ankylosing spondylitis, severe psoriatic arthritis, severe chronic plaque psoriasis, severe Crohn's disease, complex refractory fistulising Crohn's disease and moderate to severe ulcerative colitis.

Infliximab (120 mg/mL injection, 1 mL pen device; 120 mg/mL injection, 1 mL syringe) (Remsima SC®) has had a change of authority level for continuing treatment of severe active rheumatoid arthritis, ankylosing spondylitis, severe psoriatic arthritis, severe chronic plaque psoriasis, severe Crohn's disease, complex refractory fistulising Crohn's disease and moderate to severe ulcerative colitis. Prescriptions for continuing treatments are now Authority required (STREAMLINED).

#### Contraception

Etonogestrel + ethinylestradiol (etonogestrel 120 microgram/24 hours + ethinylestradiol 15 microgram/24 hours vaginal drug delivery system, 3 rings) (NuvaRing®) is now listed on the PBS for contraceptive use. It is listed as an unrestricted benefit.

#### **Epileptic seizures**

Levetiracetam tablets and oral liquid and lamotrigine tablets for the treatment of epileptic seizures have had a change to their restrictions. They are now listed as a restricted benefit.

#### Prevention of vascular ischaemia associated with atherothrombotic events

Clopidogrel (75 mg tablet) (Aurobindo, USA®; Novadoz, USA®; Zentiva, UK®) for the prevention of vascular ischaemia associated with atherothrombotic events is now listed on the PBS for the current supply shortage under Section 19A. Clopidogrel is listed as an unrestricted benefit and a restricted benefit.

#### **Ventricular arrhythmias**

Disopyramide (100 mg capsule) (Rythmodan (UK)®) for the treatment of ventricular arrhythmias is now listed on the PBS for the current supply shortage under Section 19A. Disopyramide is listed as a restricted benefit.

#### Attention deficit hyperactivity disorder

Methylphenidate hydrochloride (10 mg, 20 mg, 30 mg, 40 mg modified release capsules) (RITALIN LA 10mg (Switzerland)®; RITALIN LA 20mg (Switzerland)®; RITALIN LA 30mg (Switzerland)®; RITALIN LA 40mg (Switzerland)®) for the treatment of attention deficit hyperactivity disorder is now listed on the PBS for the current supply shortage under Section 19A. Authority applications can be made using the Online PBS Authorities system or by telephone.

#### 1 November 2025 delisted PBS listings

#### Subfoveal choroidal neovascularisation (CNV)

Aflibercept (8 mg/0.07 mL injection, 0.07 mL vial) (Eylea®) no longer has a listing for Grandfather arrangements.

#### Proven inborn errors of protein metabolism

Triglycerides long chain with glucose polymer (oral liquid, 27 x 200 mL cartons) (Sno-Pro®) has been delisted.

#### **Important Information**

## 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 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 prescribing PBS medicines 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.

#### **More information**

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