

Pharmaceutical Benefits Scheme (PBS) Listings

1 September 2025

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

Uncontrolled severe asthma

Dupilumab (200 mg/1.14 mL injection, 2 x 1.14 mL syringes; 200 mg/1.14 mL injection, 2 x 1.14 mL pen devices; 300 mg/2 mL injection, 2 x 2 mL syringes; 300 mg/2 mL injection, 2 x 2 mL pen devices) (Dupixent®) is now listed on the PBS for the treatment of uncontrolled severe asthma in patients aged 6 to less than 12 years. Authority applications for initial, grandfather and continuing treatments can be made using the Online PBS Authorities system or in writing.

Chronic severe atopic dermatitis; uncontrolled severe asthma

Dupilumab (200 mg/1.14 mL injection, 2 x 1.14 mL pen devices; 300 mg/2 mL injection, 2 x 2 mL pen devices) (Dupixent®) is now listed on the PBS for the treatment of chronic severe atopic dermatitis and uncontrolled severe asthma. Authority applications for initial and continuing treatments for chronic severe atopic dermatitis can be made either in real-time using the Online PBS Authorities system or by telephone. Authority applications for initial and continuing treatments for uncontrolled severe asthma can be made using the Online PBS Authorities system or in writing.

Cystic fibrosis

Ivacaftor (13.4 mg granules, 56 sachets) (Kalydeco®) is now listed on the PBS for the treatment of cystic fibrosis in patients aged 1 month or older. Authority applications for initial and continuing treatments can be made either in real-time using the Online PBS Authorities system or in writing.

Fibrodysplasia ossificans progressiva (FOP)

Palovarotene (1 mg capsule; 1.5 mg capsule; 2.5 mg capsule; 5 mg capsule) (Sohonos®) is now listed on the PBS for the 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).

Severe psoriatic arthritis; ankylosing spondylitis; severe chronic plaque psoriasis; moderate to severe hidradenitis suppurativa

Secukinumab (300 mg/2 mL injection, 2 mL pen device) (Cosentyx®) is now listed on the PBS for the treatment of severe psoriatic arthritis, ankylosing spondylitis, severe chronic plaque psoriasis and moderate to severe hidradenitis suppurativa.

Polycythemia vera

Ruxolitinib (5 mg tablet; 10 mg tablet; 15 mg tablet; 20 mg tablet) (Jakavi®) is now listed on the PBS for the treatment of polycythemia vera. Authority applications for initial treatment can be made either in real-time using the Online PBS Authorities system or in writing. Applications for balance of initial treatment and continuing treatment can be made either in real-time using the Online PBS Authorities system or by telephone.

Neuromyelitis optica spectrum disorder (NMOSD)

Ravulizumab (300 mg/3 mL injection, 3 mL vial; 1.1 g/11 mL injection, 11 mL vial) (Ultomiris®) has had a change in the restrictions for the treatment of NMOSD. Authority applications for initial and grandfather treatments can be made using the Online PBS Authorities system or in writing. Applications for continuing treatment can be made either in real-time using the Online PBS Authorities system or by telephone.

Severe chronic plaque psoriasis - paediatric patients

Adalimumab (20 mg/0.2 mL injection, 0.2 mL syringe; 20 mg/0.4 mL injection, 0.4 mL syringe; 40 mg/0.4 mL injection, 0.4 mL syringe; 40 mg/0.4 mL injection, 0.4 mL pen device; 40 mg/0.8 mL injection, 0.8 mL syringe; 40 mg/0.8 mL injection, 0.8 mL pen device) (multiple brands) is now listed for the treatment of severe chronic plaque psoriasis in patients under 18 years of age. Authority applications for initial, change or recommencement of treatment can be made using the Online PBS Authorities system or in writing. Applications for continuing treatment can be made either in real-time using the Online PBS Authorities system or in writing.

Severe Crohn's disease - paediatric patients

Adalimumab (20 mg/0.2 mL injection, 0.2 mL syringe; 20 mg/0.4 mL injection, 0.4 mL syringe; 40 mg/0.4 mL injection, 0.4 mL syringe; 40 mg/0.4 mL injection, 0.4 mL pen device; 40 mg/0.8 mL injection, 0.8 mL syringe; 40 mg/0.8 mL injection, 0.8 mL pen device; 80 mg/0.8 mL injection, 0.8 mL syringe; 80 mg/0.8 mL injection, 0.8 mL pen device) (multiple brands) has had a change in the restrictions for the treatment of severe Crohn's disease in patients aged 6 to 17 years inclusive. Authority applications for initial, change or recommencement of treatment, and continuing treatment can be made either in real-time using the Online PBS Authorities system or in writing.

Moderate to severe ulcerative colitis - paediatric patients

Adalimumab (20 mg/0.2 mL injection, 0.2 mL syringe; 20 mg/0.4 mL injection, 0.4 mL syringe; 40 mg/0.4 mL injection, 0.4 mL syringe; 40 mg/0.4 mL injection, 0.4 mL pen device; 40 mg/0.8 mL injection, 0.8 mL syringe; 40 mg/0.8 mL injection, 0.8 mL pen device; 80 mg/0.8 mL injection, 0.8 mL syringe; 80 mg/0.8 mL injection, 0.8 mL pen device) (multiple brands) has had a change in the restrictions for the treatment of moderate to severe ulcerative colitis in patients aged 6 years of age or older. Authority applications for initial, change or recommencement of treatment can be made using the Online PBS Authorities system or in writing. Applications for continuing treatment can be made either in real-time using the Online PBS Authorities system or by telephone.

Giant cell tumour of bone; bone metastases

Denosumab (120 mg/mL injection, 1 mL syringe) (Xgeva®) is now listed on the PBS for the treatment of giant cell tumour of bone and bone metastases. Prescriptions for treatment are Authority required (STREAMLINED).

Attention deficit hyperactivity disorder

Methylphenidate hydrochloride (10 mg, 20 mg, 30 mg, 60 mg modified release capsules) (Methylphenidate Orifarm 10 mg (Sweden)®; Methylphenidate Orifarm 20 mg (Sweden)®; Methylphenidate Orifarm 30 mg (Sweden)®; Methylphenidate Orifarm 60 mg (Denmark)®) 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 either in real-time using the Online PBS Authorities system or by telephone.

Chronic hepatitis B and chronic hepatitis C

Peginterferon alfa-2a (135 microgram/0.5 mL injection, 4 x 0.5 mL syringes; 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes) (Pegasys (Ireland)®) for the treatment of chronic hepatitis B and chronic hepatitis C is now listed on the PBS for the current supply shortage under Section 19A. Peginterferon alfa-2a is listed as an unrestricted benefit.

Hypertension

Prazosin (2 mg capsule) (Prazosin Hydrochloride Capsules, USP 2 mg (Novitium Pharma, USA)®) for the treatment of hypertension is now listed on the PBS for the current supply shortage under Section 19A. Prazosin is listed as a restricted benefit.

1 September 2025 delisted PBS listings

Hereditary transthyretin amyloidosis

Patisiran (10 mg/5 mL injection, 5 mL vial) (Onpattro®) no longer has a listing for Grandfather arrangements.

Stage IV renal cell carcinoma

Cabozantinib (20 mg tablet; 40 mg tablet; 60 mg tablet) (Cabometyx®) no longer has a listing for Grandfather arrangements.

PBS Authorities – Changes from 1 September 2025

We understand having access to PBS-subsidised medicines can be critical to patient care. That's why Services Australia and the Department of Health, Disability and Ageing are continuing to work together to increase the number of PBS medicines that can be requested and approved using the Online PBS Authorities system (the system).

From 1 September 2025, you will be able to use the system to apply for authority approval and provide evidence digitally for the following medicines. These changes will make it easier for you to request authority approval for these medicines from Services Australia. You will no longer need to submit the written authority application form, details of the proposed prescriptions and test results for certain medicines and treatment phases.

Treatment of severe chronic plaque psoriasis

Authority applications for initial, change or recommencement and continuing treatments for patients 18 years of age or older with adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab can now be made either using the Online PBS Authorities system or in writing.

Applications for initial, change or recommencement and continuing treatments for patients under 18 years of age with adalimumab and ustekinumab can now be made either using the Online PBS Authorities system or in writing.

Applications for initial, change or recommencement and re-treatment with etanercept can now be made either using the Online PBS Authorities system or by telephone. Completion of course is Authority required (STREAMLINED).

Treatment of Crohn's disease - paediatric patients

Authority applications for initial, change or recommencement and continuing treatments with adalimumab and infliximab can now be made either using the Online PBS Authorities system or in writing.

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.

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 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.