

Pharmaceutical Benefits Scheme (PBS) Listings

1 January 2025

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

Severe Crohn's disease ; moderate to severe ulcerative colitis ; severe active juvenile idiopathic arthritis; complex refractory fistulising Crohn's disease ; severe active rheumatoid arthritis ; severe psoriatic arthritis; ankylosing spondylitis ; severe chronic plaque psoriasis ; moderate to severe hidradenitis suppurativa ; vision-threatening non-infectious uveitis

Adalimumab (Hyrimoz®) (40 mg/0.4 mL injection, 2 x 0.4 mL pen devices) is a new strength of biosimilar now listed on the PBS for the treatment of severe Crohn's disease; moderate to severe ulcerative colitis ; severe active juvenile idiopathic arthritis; complex refractory fistulising Crohn's disease ; severe active rheumatoid arthritis ; severe psoriatic arthritis; ankylosing spondylitis ; severe chronic plaque psoriasis ; moderate to severe hidradenitis suppurativa ; vision-threatening non-infectious uveitis.

Acute lymphoblastic leukaemia

Dasatinib (20 mg tablet; 50 mg tablet; 70 mg tablet; 100 mg tablet) has had a change of restriction to allow subsidised access beyond 24 months of treatment. Authority applications for first line initial treatment and second line initial treatment can be made in writing. Authority applications for continuing treatment can be made either in real-time using the Online PBS Authorities system or by telephone.

Imatinib (100 mg capsule; 400 mg capsule; 100 mg tablet; 400 mg tablet; 600 mg tablet) has had a change of restriction to allow subsidised access beyond 24 months of treatment. Authority applications for first line initial treatment can be made either in real-time using the Online PBS Authorities system or by telephone. Prescriptions for continuing treatment are Authority required (STREAMLINED).

Late onset growth hormone deficiency

Somatropin (Genotropin GoQuick®; Norditropin FlexPro®; Saizen®) has had a change of restriction to enable adults with established hypothalamic-pituitary disease to be eligible for access to somatropin without the requirement to undergo dynamic testing (e.g. insulin tolerance test or glucagon provocative test). Authority applications for initial treatment can be made either in real-time using the Online PBS Authorities system or in writing. Authority applications for continuing treatment can be made either in real-time using the Online PBS Authorities system or by telephone.

Pre-symptomatic spinal muscular atrophy (SMA)

Risdiplam (Evrysdi®) (750 microgram/mL powder for oral liquid, 80 mL) has had an amendment to the treatment criteria. Authority applications for initial treatment can be made either using the Online PBS Authorities system or in writing. Authority applications for continuing treatment can be made either using the Online PBS Authorities system or by telephone.

Complex refractory Fistulising Crohn's disease

Ustekinumab (Stelara®) (90 mg/mL injection, 1 mL syringe) for the treatment of complex refractory Fistulising Crohn's disease has had an amendment to remove the grandfather restriction. Authority applications for initial and continuing treatments can be made in writing.

Metastatic breast cancer

Olaparib (Lynparza®) (100 mg tablet; 150 mg tablet) is now listed on the PBS for the treatment of human epidermal growth factor 2 (HER2) negative metastatic breast cancer with a confirmed BRCA1 or BRCA2 mutation. Authority applications for initial and continuing treatments can be made either in real-time using the Online PBS Authorities system or by telephone.

Castration resistant metastatic carcinoma of the prostate

Talazoparib (Talzenna®) (100 microgram capsule; 250 microgram capsule; 350 microgram capsule; 500 microgram capsule) is now listed on the PBS for the treatment of castration resistant metastatic

carcinoma of the prostate. Authority applications for treatment can be made either in real-time using the Online PBS Authorities system or by telephone.

Severe active juvenile idiopathic arthritis

Tofacitinib (Xeljanz®) (5 mg tablet; 1 mg/mL oral liquid, 240 mL) for the treatment of severe active juvenile idiopathic arthritis has had an amendment to remove the grandfather restriction with a supply only arrangement for 12 months. Authority applications for initial treatment can be made either in real-time using the Online PBS Authorities system or by telephone. Prescriptions for continuing treatment are Authority required (STREAMLINED).

Schizophrenia

Risperidone (Risvan®) (75 mg modified release injection [1 syringe] (& inert substance diluent [0.383 mL syringe], 1 pack; 100 mg modified release injection [1 syringe] (& inert substance diluent [0.49 mL syringe], 1 pack) is now listed on the PBS for the treatment of schizophrenia. Prescriptions for treatment are Authority required (STREAMLINED).

1 January 2025 delisted PBS listings

Severe dry eye syndrome

Hypromellose + carbomer-980 (Genteal gel®; HPMC PAA®) (hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g) has been delisted from the PBS with a 6-month supply only arrangement.

PBS Authorities – Changes from 1 January 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 and Aged Care 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 January 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 childhood onset/late onset growth hormone deficiency with somatropin:

- Authority applications for initial treatment can be made either in real-time using the Online PBS Authorities system or in writing. Authority applications for continuing treatment can be made either in real-time using the Online PBS Authorities system or by telephone.

Reminders

Correct online authority number

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.

PBS Authorities – written authority application forms

It is important to note, that as of 1 November 2024, the forms for spinal muscular atrophy (SMA) have been completely revamped. Ensure you use the most recently published written authority application form when applying for PBS-subsidised medicines for SMA and any other PBS program. 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.

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.

Esomeprazole 40 mg to treat complex gastro-oesophageal reflux disease (GORD)

PBS-subsidised prescriptions for esomeprazole 40 mg enteric tablets and capsules for the treatment of complex GORD must only be written by a:

- gastroenterologist; or
- a surgeon with expertise in the upper gastrointestinal tract.

General Practitioners (GPs) and other prescribers cannot write PBS-subsidised prescriptions for esomeprazole 40 mg tablets/capsules for complex GORD. Do not refer patients to their GPs to request these prescriptions as the authority request will be rejected.

Authority applications can be requested and approved in 'real time' using the Online PBS Authorities system. The system makes it easier for you to request an authority approval from Services Australia by providing an immediate processing response, avoiding any postage and processing delays.

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.

Online PBS Authorities Survey

We would appreciate if you could take a moment to complete the Online PBS Authorities Survey. Your feedback will assist in ensuring the communication material we provide suits your needs.

<https://survey.websurveycreator.com/s.aspx?s=5d81e8f2-371e-4763-87f8-77bcb8eddf48>