

Pharmaceutical Benefits Scheme (PBS) Listings 1 September 2024

Please find below information relating to new and amended Pharmaceutical Benefits Scheme (PBS) listings implemented on **1 September 2024**.

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.

Release of stage 3 for 60-day prescriptions

From 1 September 2024, the final release for 60-day prescriptions will be made available to many patients living with an ongoing health condition. Patients who are stable on their current treatment will be able to receive twice the medication for the cost of a single prescription.

Stage 3, from 1 September 2024, includes 264 medicines (766 PBS items) and represents roughly one third of all the medicines eligible for 60-day prescriptions. The 766 PBS items include the different forms (strength and presentation) of the stage 3 medicines. For more information go to health.gov.au

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Crizotinib, entrectinib, alectinib, brigatinib, ceritinib and lorlatinib have had a change to the restriction for the treatment of Stage IIIB (locally advanced) or Stage IV (metastatic) NSCLC. Authority applications for initial treatment with crizotinib and entrectinib can be made either in real-time using the Online PBS Authorities system or in writing. Authority applications for initial treatment with alectinib, brigatinib, ceritinib and lorlatinib can be made either in real-time using the Online PBS Authorities system or by telephone. Authority applications for continuing treatment can be made either in real-time using the Online PBS Authorities system or by telephone.

Fabry disease

Migalastat (Galafold®) (123 mg capsule) is now listed on the PBS for the treatment of Fabry disease. Authority applications for initial and grandfather treatments 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.

Solid tumours with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion

Larotrectinib (Vitrakvi®) (25 mg capsule; 100 mg capsule; 20 mg/mL oral liquid, 2 x 50 mL) has had a change to the restriction for the continuing treatment of solid tumours with confirmed NTRK gene fusion. 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.

Unresectable and/or metastatic HER2-low breast cancer

Trastuzumab deruxtecan (Enhertu®) (100 mg injection, 1 vial) is now listed on the PBS for the treatment of unresectable and/or HER2-low breast cancer. Authority applications can be made either in real-time using the Online PBS Authorities system or by telephone.

Cytomegalovirus infection and disease

Ganciclovir (Cymevene®; GANCICLOVIR SXP®) (500 mg injection); valganciclovir (Valcyte®) (50 mg/mL powder for oral liquid, 100 mL); valganciclovir (Valganciclovir Sandoz®; Valganciclovir Viatris®) (450 mg tablet) has had a change to the restriction for the treatment of cytomegalovirus infection and disease. Prescriptions for treatment are Authority Required (STREAMLINED).

Mild to moderate Crohn's disease

Budesonide (Budenofalk®) (3 mg enteric capsule) is now listed on the PBS for the treatment of mild to moderate Crohn's disease. Prescriptions for initial and continuing treatments are Authority Required (STREAMLINED).

Stage IV renal cell carcinoma (RCC)

Cabozantinib (Cabometyx®) (20 mg tablet; 40 mg tablet; 60 mg tablet) has had a change to the restriction for the treatment of Stage IV RCC. Prescriptions for initial, grandfather and continuing treatments are Authority Required (STREAMLINED).

Advanced (unresectable and/or metastatic) leiomyosarcoma or liposarcoma

Trabectedin (Yondelis®) (1 mg injection) has had an amendment to remove the grandfather restriction. Prescriptions for initial and continuing treatments are Authority Required (STREAMLINED).

Chronic obstructive pulmonary disease (COPD)

Tiotropium (Tiotropium Lupin™) (18 microgram powder for inhalation, 30 capsules) is now listed on the PBS for the treatment of COPD. It is listed as a restricted benefit.

Severe dry eye syndrome

All ocular lubricants that have previously been listed for the treatment of severe dry eye syndrome, including Sjogren's syndrome, have had any reference to Sjogren's syndrome removed.

Trachoma

Azithromycin (Azithromycin (Zydus, USA)®) (200 mg/5 mL powder for oral liquid, 15 mL) is now listed on the PBS for the current supply shortage under Section 19A. It is listed as a restricted benefit.

Bacterial infections

Amoxicillin + clavulanic acid (CLAVULIN-125F (GlaxoSmithKline, Canada)®) (125 mg/5mL + 31.25 mg/5 mL powder for oral liquid, 100 mL) is now listed on the PBS for the current supply shortage under Section 19A. It is listed as a restricted benefit.

1 September 2024 delisted PBS listings

Proven inborn errors of protein metabolism

Triglycerides long chain with glucose polymer (ProZero®) (oral liquid, 18 x 250 mL cartons) has been delisted from the PBS with a 6 month supply only arrangement.

PBS Authorities – Changes from 1 September 2024

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).

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. Instead, you will be able to use the system to apply for authority approval and provide evidence digitally.

The changes being made from 1 September 2024 include the following medicines:

- Mavacamten for the treatment of symptomatic obstructive hypertrophic cardiomyopathy

Commented [JK1]: Tan - FYI Jools and Anne have suggested moving all 'transformation' changes into its own section.

Would we include this info in the Listing peak body comms because there aren't any changes to the actual listings are there?

Commented [MTA2R1]: Did we include last month's transformation in the listing Comms?

Authority applications for initial and grandfather treatments can now be made either 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.

- Omalizumab for the treatment of severe chronic spontaneous urticaria
Authority applications for initial treatment can now be made either 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.
- Teduglutide for the treatment of type III short bowel syndrome with intestinal failure
Authority applications for initial and continuing treatments can now be made either using the Online PBS Authorities system or in writing.

Reminders

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.

Changes to the HPOS upload function for Written Authorities

From 1 September 2024, you may notice that the HPOS upload function will look slightly different:

- 'PBS – Authority Application and Prescriptions' under 'Form Category' will become 'PBS Authorities'
- Form Categories will be listed in alphabetical order
- Abbreviations for conditions under 'Form Type' have been removed.

For more information about HPOS Form Upload visit www.servicesaustralia.gov.au/hpos

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.