

Please find below information relating to new and amended Pharmaceutical Benefits Scheme (PBS) listings implemented on **1 May 2024**. [Frequently Asked Questions \(FAQs\)](#) relating to access and use of the Online PBS Authorities system are also attached. This information may be of interest to your members.

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.

Symptomatic obstructive hypertrophic cardiomyopathy

Mavacamten (Camzyos®) (2.5 mg capsule; 5 mg capsule; 10 mg capsule; 15 mg capsule) is now listed on the PBS for the treatment of symptomatic obstructive hypertrophic cardiomyopathy. 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.

Transthyretin amyloid cardiomyopathy

Tafamidis (Vyndamax®) (61 mg capsule) is now listed on the PBS for the treatment of transthyretin amyloid cardiomyopathy. Authority applications for initial and grandfather treatments 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.

Severe aplastic anaemia

Eltrombopag (Revolade®) (25 mg tablet; 50 mg tablet) is now listed on the PBS for the treatment of severe aplastic anaemia. Authority applications for initial and grandfather treatments can be made either in real-time using the Online PBS Authorities system or in writing. Authority applications for continuing second-line treatment can be made either in real-time using the Online PBS Authorities system or by telephone.

Severe chronic plaque psoriasis

Risankizumab (Skyrizi®) (150 mg/mL injection, 1 mL pen device) is now listed on the PBS for the treatment of severe chronic plaque psoriasis. Authority applications for initial and continuing treatments can be made in writing. Authority applications for balance of supply can be made either in real-time using the Online PBS Authorities system or by telephone.

Pulmonary arterial hypertension (PAH)

Ambrisentan (5 mg tablet; 10 mg tablet), bosentan (62.5 mg tablet; 125 mg tablet), epoprostenol (500 microgram injection; 1.5 mg injection), iloprost (20 microgram/2 mL inhalation solution, 30 x 2 mL ampoules), macitentan (10 mg tablet), sildenafil (20 mg tablet) and tadalafil (20 mg tablet) have had an amendment to remove the grandfather restriction. Authority applications for initial 1 treatment can be made either in real-time using the Online PBS Authorities system or in writing. Authority applications for initial 2, initial 3 and continuing treatments can be made either in real-time using the Online PBS Authorities system or by telephone.

Paroxysmal nocturnal haemoglobinuria (PNH)

Pegcetacoplan (Empaveli™) (1.08 g/20 mL injection, 20 mL vial) has had an amendment to remove the grandfather restriction. Authority applications for initial, continuing and returning treatment can be made in writing.

Newly diagnosed systemic light chain amyloidosis

Daratumumab (Darzalex SC®) (1.8 g/15 mL injection, 15 mL vial) has had an amendment to remove the grandfather restriction. 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.

Diabetic macular oedema (DMO) & subfoveal choroidal neovascularisation (CNV)

Faricimab (Vabysmo®) (6 mg/0.05 mL intraocular injection, 0.05 mL vial) has had an amendment to remove the grandfather restriction. Authority applications for initial treatment can be made either in real-time using the Online PBS Authorities system or in writing. Prescriptions for continuing treatment are Authority Required (STREAMLINED).

Early Breast Cancer

Abemaciclib (Verzenio®) (50 mg tablet; 100 mg tablet; 150 mg tablet) is now listed on the PBS for the treatment of early breast cancer. Authority applications can be made either in real-time using the Online PBS Authorities system or by telephone.

Moderate to severe pruritus (itching) associated with chronic kidney disease

Difelikefalin (Korsuva®) (50 microgram/mL injection, 12 x 1 mL vials) is now listed on the PBS for the treatment of moderate to severe pruritus (itching) associated with chronic kidney disease. Authority applications for initial, grandfather and continuing treatments can be made either in real-time using the Online PBS Authorities system or by telephone.

Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)

Cemiplimab (Libtayo®) (350 mg/7 mL injection, 7 mL vial) has had an amendment to remove the grandfather restriction. Authority applications for initial and continuing treatments can be made either in real-time using the Online PBS Authorities system or by telephone.

X-linked hypophosphataemia

Burosumab (Crysvita®) (10 mg/mL injection, 1 mL vial; 20 mg/mL injection, 1 mL vial; 30 mg/mL injection, 1 mL vial) has had an amendment to remove the grandfather restriction. Authority applications for initial and continuing treatments can be made either in real-time using the Online PBS Authorities system or by telephone.

Relapsed and/or refractory multiple myeloma

Daratumumab (Darzalex®) (100 mg/5 mL injection, 5 mL vial; 400 mg/20 mL injection, 20 mL vial) has had an amendment to remove the grandfather restriction. Authority applications for initial and continuing treatments can be made either in real-time using the Online PBS Authorities system or by telephone.

Chronic heart failure

Vericiguat (Verquvo®) (2.5 mg tablet; 5 mg tablet; 10 mg tablet) has had an amendment to remove the grandfather restriction. 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).

Familial heterozygous hypercholesterolaemia & non-familial hypercholesterolaemia

Inclisiran (Leqvio®) (284 mg/1.5 mL injection, 1.5 mL syringe) has had a change in the number of repeats allowed for continuing treatment. Authority applications for initial and grandfather treatments can be made either in real-time using the Online PBS Authorities system or by telephone. Prescriptions for continuing treatment are Authority Required (STREAMLINED).

Evolocumab (Repatha®) (140 mg/mL injection, 1 mL pen device; 420 mg/3.5 mL injection, 3.5 mL cartridge) and alirocumab (Praluent®) (75 mg/mL injection, 2 x 1 mL pen devices; 150 mg/mL injection, 2 x 1 mL pen devices) have had a change to their restrictions for continuing treatment. 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).

Osteoporosis

Teriparatide (Teriparatide Lupin®) (250 microgram/mL injection, 2.4 mL pen device) is now listed on the PBS for the treatment of osteoporosis. Prescriptions for initial and continuing treatments are Authority Required (STREAMLINED).

Severe active rheumatoid arthritis

Upadacitinib (Rinvoq®) (15 mg tablet) has had a change in the authority level for subsequent continuing treatment of severe active rheumatoid arthritis. Authority applications for initial and first continuing treatments can be made in writing. Prescriptions for subsequent continuing treatment are now Authority Required (STREAMLINED). Authority applications for balance of supply can be made either in real-time using the Online PBS Authorities system or by telephone.

Advanced, metastatic or recurrent endometrial carcinoma

Dostarlimab (Jemperli®) (500 mg/10 mL injection, 10 mL vial) is now listed on the PBS for the treatment of advanced, metastatic or recurrent endometrial carcinoma. Prescriptions for initial, grandfather and continuing treatments are Authority Required (STREAMLINED).

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

Tepotinib (Tepmetko®) (225 mg tablet) has had an amendment to remove the grandfather restriction. Prescriptions for initial and continuing treatments are Authority Required (STREAMLINED).

Maple syrup urine disease

Amino acid formula with vitamins and minerals without valine, leucine, isoleucine and supplemented with arachidonic acid and docosahexaenoic acid (MSUD explore5®) (powder for oral liquid, 30 x 12.5 g sachets) is now listed on the PBS for treatment of maple syrup urine disease. It is listed as a restricted benefit.

Pyridoxine non-responsive homocystinuria

Amino acid formula with vitamins and minerals, without methionine and supplemented with arachidonic acid and docosahexaenoic acid (HCU explore5®) (powder for oral liquid, 30 x 12.5 g sachets) is now listed on the PBS for the treatment of pyridoxine non-responsive homocystinuria. It is listed as a restricted benefit.

Tyrosinaemia

Amino acid formula with vitamins and minerals, without phenylalanine, tyrosine and supplemented with arachidonic acid and docosahexaenoic acid (TYR explore5®) (powder for oral liquid, 30 x 12.5 g sachets) is now listed on the PBS for the treatment of tyrosinaemia. It is listed as a restricted benefit.

Primary hypercholesterolaemia & relief of pruritus associated with partial biliary obstruction

Colestyramine (Cholestyramine (Ascend, USA)®) (4 g powder for oral liquid, 60 pouches) for the treatment of primary hypercholesterolaemia & relief of pruritus associated with partial biliary obstruction is now listed on the PBS for the current supply shortage under Section 19A. Cholestyramine is listed as a restricted benefit and as an unrestricted benefit.

Nausea and vomiting

Prochlorperazine (Stemetil (Ireland)®) (5 mg tablet) for the treatment of nausea and vomiting is now listed on the PBS for the current supply shortage under Section 19A. Prochlorperazine is listed as an unrestricted benefit.

1 May 2024 delisted PBS listings

Severe chronic plaque psoriasis

Risankizumab (Skyrizi®) (75 mg/0.83 mL injection, 2 x 0.83 mL syringes) has been delisted from the PBS with a 6 month supply only arrangement.

Bacterial infection

Cefuroxime (Zinnat®) (125 mg/5 mL powder for oral liquid, 100 mL) has been delisted from the PBS with no supply only arrangement.

Procaine benzylpenicillin (Cilicaine®) (1.5 g/3.4 mL injection, 5 x 3.4 mL syringes) has been delisted from the PBS with no supply only arrangement.

Severe dry eye syndrome

Carbomer-974P (Poly Gel®)(0.3% eye gel, 30 x 500 mg ampoules) has been delisted from the PBS with a 6 month supply only arrangement.

Dextran-70 + hypromellose (Bion Tears®) (dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL ampoules) has been delisted from the PBS with a 6 month supply only arrangement.

Cancer

Capecitabine (Capecitabine-DRLA®)(150 mg tablet) has been delisted from the PBS with a 2 month supply only arrangement.

Proven glutaric aciduria type 1 & pyridoxine dependent epilepsy

Amino acid formula with vitamins and minerals without lysine and low in tryptophan (GA express 15®) (powder for oral liquid, 30 x 25 g sachets) has been delisted from the PBS with no supply only arrangement.

Changes to the prescription process from 1 July 2024

The Department of Health and Aged Care has reviewed and remade the following instruments: the *National Health (Listings of Pharmaceutical Benefits) Instrument 2012*, the *National Health (Prescriber bag supplies) Determination 2012*, and the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011*. As a result of the review, the *National Health (Pharmaceutical Benefits) Regulations 2017* have also been amended. For further information regarding the legislation changes go to www.legislation.gov.au.

The remade legislation will take effect on 1 April 2024 and will change Services Australia's processes for PBS Authority Required applications submitted via the post. We will no longer require the original prescription to assess your request, only the details of the proposed PBS prescription. We won't record the Authority Approval Number on the prescription or forward approved prescriptions to the patient.

A transition period will be in place from 1 April 2024, with the process changes coming into full effect on 1 July 2024.

From 1 July 2024, Services Australia will only accept details of the proposed PBS prescription (and PDF form where appropriate) when seeking PBS authority approval via the post.

Once processed, the assessment outcome will be sent to the prescriber via the post. If approved, the prescriber will need to endorse the original PBS authority prescription with the PBS Approval Number and PBS item code.

It's important to note all original prescriptions received via the post that are written on or after 1 July 2024 will be immediately returned to the prescriber. Services Australia will retain a copy of the prescription for processing.

We're updating PBS Authority prescription pads to remove the 'Tick for return to patient' checkbox. You can continue to use your residual stock as it will still be valid.

We understand having timely access to PBS-subsidised medicines can be critical to patient care. You can submit written PBS Authorities through the Health Professional Online Services (HPOS) Form Upload function. Also, most PBS Authorities can be requested and approved in 'real time' using the Online PBS Authorities system.

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.

For more information go to servicesaustralia.gov.au/hpos

Kind regards,

PBS Authorities
Pharmaceutical Benefits Branch