

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

Non-radiographic axial spondyloarthritis

Certolizumab pegol (Cimzia®), golimumab (Simponi®), secukinumab (Cosentyx®) and upadacitinib (Rinvoq®) have had a change to their restrictions to remove the age specificity for the treatment of non-radiographic axial spondyloarthritis. Authority applications for initial treatment with these agents and for grandfather treatment with upadacitinib 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.

Severe growth failure with primary insulin-like growth factor-1 deficiency

Mecasermin (Increlex®) (10 mg/mL injection, 4 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 in writing.

Pulmonary arterial hypertension

Riociguat (Adempas®) (500 microgram, 1 mg, 1.5 mg, 2 mg, 2.5 mg tablet) has had a change of restriction for the treatment of pulmonary arterial hypertension. Authority applications for initial 1 treatment can be made in writing. Authority applications for initial 2 and continuing treatments can be made either in real-time using the Online PBS Authorities system or by telephone.

Familial heterozygous hypercholesterolaemia & non-familial hypercholesterolaemia

Inclisiran (Leqvio®) (284 mg/1.5 mL injection, 1.5 mL syringe) is now listed on the PBS for the treatment of familial heterozygous hypercholesterolaemia & non-familial hypercholesterolaemia. 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) 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).

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Niraparib (Zejula®) (100 mg capsule) has had a change of restriction for the treatment of high grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer. Authority applications can be made either in real-time using the Online PBS Authorities system or by telephone.

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Acalabrutinib (Calquence®) (100 mg tablet) has had an amendment to the listing for the treatment of chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL).

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

Obinutuzumab (Gazyva®) (1 g/40 mL injection, 40 mL vial) has had an amendment to the existing listing to increase the number of repeats for the treatment of chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL). Prescriptions for treatment are Authority Required (STREAMLINED).

Relapsed or refractory Acute Myeloid Leukaemia

Gilteritinib (Xospata®) (40 mg tablet) 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

Selinexor (Xpovio®) (20 mg tablet) 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.

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 and continuing treatments can be made either in real-time using the Online PBS Authorities system or by telephone.

Primary biliary cholangitis

Obeticholic acid (Ocaliva®) (10 mg tablet, 5 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).

Asthma & chronic obstructive pulmonary disease (COPD)

Fluticasone propionate + salmeterol (Salflumix Easyhaler®) (fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations; fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations) is now listed on the PBS for the treatment of asthma & chronic obstructive pulmonary disease (COPD). Prescriptions for treatment are Authority Required (STREAMLINED).

Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Cemiplimab (Libtayo®) (350 mg/7 mL injection, 7 mL vial) is now listed on the PBS for the treatment of stage IV (metastatic) non-small cell lung cancer (NSCLC). Prescriptions for treatment are Authority Required (STREAMLINED).

Severe established osteoporosis

Teriparatide (Terrosa®) (250 microgram/mL injection, 2.4 mL pen device) is now listed on the PBS for the treatment severe established osteoporosis. Prescriptions for treatment are Authority Required (STREAMLINED).

Chronic kidney disease

Empagliflozin (Jardiance®) (10 mg tablet) is now listed on the PBS for the treatment of chronic kidney disease. Prescriptions for treatment are Authority Required (STREAMLINED).

Nausea and vomiting

Ondansetron has had a change of restriction for the treatment of nausea and vomiting. Prescriptions for treatment are Authority Required (STREAMLINED) benefit and restricted benefit.

Severe active juvenile idiopathic arthritis

Methotrexate (Trexject®) (7.5 mg/0.15 mL injection, 0.15 mL syringe, 10 mg/0.2 mL injection, 0.2 mL syringe, 15 mg/0.3 mL injection, 0.3 mL syringe, 20 mg/0.4 mL injection, 0.4 mL syringe, 25 mg/0.5 mL injection, 0.5 mL syringe) is now listed for the treatment of severe active juvenile idiopathic arthritis. Prescriptions for treatment are Authority Required (STREAMLINED).

Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx

Pembrolizumab (Keytruda®) (100 mg/4 mL injection, 4 mL vial) has had an amendment to remove the grandfather restriction. Prescriptions for treatment are Authority Required (STREAMLINED).

Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer

Avelumab (Bavencio®) (200 mg/10 mL injection, 10 mL vial) has had an amendment to remove the grandfather restriction. Prescriptions for treatment are Authority Required (STREAMLINED).

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Lacosamide (50 mg tablet, 100 mg tablet, 150 mg tablet, 200 mg tablet; 10 mg/mL oral liquid, 200 mL) has had an amendment to the existing listing for the treatment of idiopathic generalised epilepsy with primary generalised tonic-clonic seizures. Prescriptions for treatment are Authority Required (STREAMLINED).

Advanced (unresectable or metastatic) uveal melanoma

Tebentafusp (Kimmtrak®) (100 microgram/0.5 mL injection, 0.5 mL vial) has had an amendment to the existing listing for the treatment of advanced (unresectable or metastatic) uveal melanoma. Prescriptions for treatment are Authority Required (STREAMLINED).

Infertility indications other than that of Assisted Reproductive Technology

Choriogonadotropin alfa (Ovidrel®) (250 microgram/0.5 mL injection, 0.5 mL pen device) has had a change to the existing listing to increase the maximum quantity of pen devices from 1 to 4. Choriogonadotropin alfa for infertility indications other than that of Assisted Reproductive Technology is listed as a restricted benefit.

Petit mal epilepsy

Ethosuximide (Ethosuximide Essential Generics (UK)®) (250 mg capsule) for the treatment of petit mal epilepsy is now listed on the PBS for the current supply shortage under Section 19A. Ethosuximide is listed as an unrestricted benefit.

1 April 2024 delisted PBS listings

HIV infection

Abacavir + lamivudine + zidovudine (Trizivir®) (300 mg + 150 mg + 300 mg tablet) has been delisted from the PBS with no supply only arrangement.

Fosamprenavir (Telzir®) (700 mg tablet) has been delisted from the PBS with no supply only arrangement.

For lubricating dry, irritated and tired eyes

Retinol palmitate + paraffin (VitA-POS®) (retinol palmitate 0.0138% + paraffin eye ointment) has been delisted from the PBS with a 6 month supply only arrangement.

Menopausal hormone therapy

Estradiol (Climara®) (25 microgram/24 hours patch, 50 microgram/24 hours patch, 75 microgram/24 hours patch, 100 microgram/24 hours patch) has been delisted from the PBS with a 6 month 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 a photocopy of the original PBS authority prescription (and PDF form where appropriate) if submitted via the post. The photocopy must be legible and contain all information required for the authority request to be processed by Services Australia.

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