Pharmaceutical Benefits Scheme (PBS) Listings 1 October 2024

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

Moderate to severe ulcerative colitis
Etrasimod (Velsipity®) (2 mg tablet) is now listed on the PBS for the treatment of moderate to severe ulcerative colitis. 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.

Multiple myeloma; relapsed and/or refractory multiple myeloma
Lenalidomide (Lenalide®) (20 mg capsule) is now listed on the on the PBS for the treatment of multiple myeloma and relapsed and/or refractory multiple myeloma. Authority applications for initial dual and triple therapy for the treatment of newly diagnosed disease, and authority applications for initial treatment of progressive disease can be made either in real-time using the Online PBS Authorities system or in writing. Authority applications for continuing dual and triple therapy for the treatment of newly diagnosed disease and authority applications for continuing treatment of progressive disease can be made either in real-time using the Online PBS Authorities system or by telephone. Authority applications for initial and continuing triple therapy to treat relapsed and/or refractory multiple myeloma can be made either in real-time using the Online PBS Authorities system or by telephone.

Complex refractory fistulising Crohn's disease; severe Crohn's disease; moderate to severe ulcerative colitis; moderate to severe hidradenitis suppurativa; severe chronic plaque psoriasis
Adalimumab (Yuflyma®) (80 mg/0.8 mL injection, 0.8 mL pen device; 80 mg/0.8 mL injection, 0.8 mL syringe) is now listed on the PBS for the treatment of complex refractory fistulising Crohn's disease; severe Crohn's disease; moderate to severe ulcerative colitis; moderate to severe hidradenitis suppurativa; severe chronic plaque psoriasis.

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 (Hadlima®) (40 mg/0.4 mL injection, 2 x 0.4 mL pen devices; 40 mg/0.4 mL injection, 2 x 0.4 mL syringes) is 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.

Severe psoriatic arthritis
Bimekizumab (Bimzelx®) (160 mg/mL injection, 2 x 1 mL pen devices) is now listed on the PBS for the treatment of severe psoriatic arthritis. Authority applications for initial, grandfather and continuing treatments can be made in writing.

Ankylosing spondylitis
Bimekizumab (Bimzelx®) (160 mg/mL injection, 2 x 1 mL pen devices) is now listed on the PBS for the treatment of ankylosing spondylitis. Authority applications for initial, grandfather and continuing treatments can be made in writing.

Tofacitinib (Xeljanz®) (5 mg tablet) for the treatment of ankylosing spondylitis has had an amendment to remove the grandfather restriction. Authority applications for initial and continuing treatments can be made in writing.

Non-radiographic axial spondyloarthritis

Bimekizumab (Bimzelx®) (160 mg/mL injection, 2 x 1 mL pen devices) is now listed on the PBS for the treatment of non-radiographic axial spondyloarthritis. Authority applications for initial and grandfather treatments can be made in writing. Applications for continuing, change or recommencement of treatment can be made either in real-time using the Online PBS Authorities system or by telephone.

Upadacitinib (Rinvoq®) (15 mg modified release tablet) for the treatment of non-radiographic axial spondyloarthritis has had an amendment to remove the grandfather restriction. Authority applications for initial treatment can be made 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
Bimekizumab (Bimzelx®) (160 mg/mL injection, 2 x 1 mL pen devices) for the treatment of severe chronic plaque psoriasis has had an amendment to remove the grandfather restriction. Authority applications for initial and continuing treatments can be made in writing.

Diabetic macular oedema (DMO)
Aflibercept (Eylea®) (8 mg/0.07 mL injection, 0.07 mL vial) is now listed on the PBS for the treatment of DMO. Authority applications for initial and grandfather treatments can be made either in real-time using the Online PBS Authorities system or in writing. Prescriptions for continuing treatment are Authority required (STREAMLINED).

Subfoveal choroidal neovascularisation (CNV) secondary to age-related macular degeneration (AMD)
Aflibercept (Eylea®) (8 mg/0.07 mL injection, 0.07 mL vial) is now listed on the PBS for the treatment of CNV secondary to AMD. Authority applications for initial and grandfather treatments can be made either in real-time using the Online PBS Authorities system or in writing. Prescriptions for continuing treatment are Authority required (STREAMLINED).

Uncontrolled severe asthma
Mepolizumab (Nucala®) (100 mg/mL injection, 1 mL pen device) has had a change to the restriction to remove the oral corticosteroid requirement within the definition of 'optimised asthma therapy' to align with the current treatment guidelines. Authority applications for initial treatment, change or recommencement of treatment and continuing treatments can be made in writing.

Severe Crohn's disease
Vedolizumab (Entyvio®) (300 mg injection, 1 vial; 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices) has had a change to the restriction to allow an additional dose of vedolizumab 300 mg at Week 10 for initial treatment. Authority applications for initial and continuing treatments can be made in writing. Authority applications for the additional dose at Week 10 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)
Ibrutinib (Imbruvica®) (140 mg capsule; 280 mg tablet; 420 mg tablet) is now listed on the PBS for the treatment of CLL or SLL. Authority applications for initial, grandfather and continuing treatments can be made either in real-time using the Online PBS Authorities system or by telephone.

Anti-neutrophil cytoplasmic autoantibody (ANCA) associated vasculitis
Avacopan (Tavneos®) (10 mg capsule) is now listed on the PBS for the treatment of anti-neutrophil cytoplasmic autoantibody (ANCA) associated vasculitis. Authority applications can be made either in real-time using the Online PBS Authorities system or by telephone.

Severe asthma
Beclometasone + formoterol + glycopyrronium (Trimbow®) (Beclometasone dipropionate 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations) is now listed on the PBS for the treatment of severe asthma. Prescriptions for treatment are Authority required (STREAMLINED).

Established atherosclerotic cardiovascular disease with hypertriglycerideaemia
Icosapent ethyl (Vazkepa®) (998 mg capsule) is now listed on the PBS for the treatment of established atherosclerotic cardiovascular disease with hypertriglyceridaemia. Prescriptions for initial and continuing treatments are Authority required (STREAMLINED).

Multiple sclerosis
Siponimod (Mayzent®) (1 mg tablet) is now listed on the PBS for the treatment of multiple sclerosis. Prescriptions for initial and continuing treatments are Authority required (STREAMLINED).

Advanced carcinoma of the cervix
Pembrolizumab (Keytruda®) (100 mg/4 mL injection, 4 mL vial) for the treatment of advanced carcinoma of the cervix has had an amendment to remove the grandfather restriction. Prescriptions for initial and continuing treatments are Authority Required (STREAMLINED).

Cancer treatment
Bevacizumab (Vegzelma®) (100 mg/4 mL injection, 4 mL vial; 400 mg/16 mL injection, 16 mL vial) is a new biosimilar now listed on the PBS for cancer treatment. It is listed as an unrestricted benefit.

Elevated intraocular pressure
Timolol (Timoptol-LA 0.5% (Santen Oy, Finland)®) (0.5% eye drops) is now listed on the PBS for the current supply shortage under Section 19A. It is listed as an unrestricted benefit.

PBS Authorities – Changes from 1 October 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).

From 1 October 2024, 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.

- Ivacaftor; lumacaftor+ivacaftor; tezacaftor+ivacaftor; elexacaftor+tezacafter+ivacaftor for the treatment of cystic fibrosis

  Authority applications for initial and continuing treatments can now be made either using the Online PBS Authorities system or in writing.
- Mepolizumab for chronic rhinosinusitis with nasal polyps

  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.

Reminders

Ensuring you are proving 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.