

Pharmaceutical Benefits Scheme (PBS) Listings

1 March 2025

Please find below information relating to new and amended Pharmaceutical Benefits Scheme (PBS) listings implemented on **1 March 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 (80 mg/0.8 mL injection, 0.8 mL pen device) (Hyrimoz®) 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.

Precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)

Blinatumomab (38.5 microgram injection [1 vial] (& inert substance solution [10 mL vial], 1 pack) (Blinicyto®) is now listed on the PBS for the treatment of Pre-B-cell ALL. Authority applications for initial and grandfather treatments 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.

Retinal vein occlusion

Faricimab (6 mg/0.05 mL intraocular injection, 0.05 mL vial) (Vabysmo®) is now listed on the PBS for the treatment of branch or central retinal vein occlusion with macular oedema. 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).

Severe psoriatic arthritis

Risankizumab (150 mg/mL injection, 1 mL pen device) (Skyrizi®) 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.

Endogenous Cushing's syndrome

Osilodrostat (1 mg tablet; 5 mg tablet) (Isturisa®) is now listed on the PBS for the treatment of endogenous Cushing's syndrome. Authority applications for initial, grandfather and continuing treatments can be made either in real-time using the Online PBS Authorities system or by telephone.

Multiple sclerosis

Fingolimod (250 microgram capsule; 500 microgram capsule) (Gilenya®); ofatumumab (20 mg/0.4 mL injection, 0.4 mL pen device) (Kesimpta®); siponimod (250 microgram tablet; 1 mg tablet; 2 mg tablet) (Mayzent®) has had an amendment to the listing to allow prescribing by nurse practitioners in consultation with a specialist physician. Prescriptions for treatment are Authority required (STREAMLINED).

Non-familial hypercholesterolaemia & familial heterozygous hypercholesterolaemia

Inclisiran (284 mg/1.5 mL injection, 1.5 mL syringe) (Leqvio®) has had an amendment to the restriction level. Prescriptions for treatment are now Authority required (STREAMLINED). There has also been an amendment to the listing to allow prescribing by nurse practitioners in consultation with a specialist physician.

Chronic heart failure

Sacubitril + valsartan (sacubitril 24.3 mg + valsartan 25.7 mg tablet; sacubitril 48.6 mg + valsartan 51.4 mg tablet; sacubitril 97.2 mg + valsartan 102.8 mg tablet) (Entresto®) has had an amendment to the listing to allow treatment initiation by nurse practitioners. Prescriptions for treatment are Authority required (STREAMLINED).

Contraception

Drospirenone + ethinylestradiol (drospirenone 3 mg + ethinylestradiol 20 microgram tablet [24] (&) inert substance tablet [4], 28 or 3 x 28) (Yaz®); (drospirenone 3 mg + ethinylestradiol 30 microgram tablet [21] (&) inert substance tablet [7], 28 or 3 x 28) (Yasmin®) is now listed on the PBS for contraceptive use. Drospirenone + ethinylestradiol is listed as an unrestricted benefit.

Menopausal hormone therapy

Estradiol (0.06% (750 microgram/actuation) gel, 64 actuations) (Estrogel®); progesterone (100 mg capsule) (Prometrium®); progesterone (&) estradiol (progesterone 100 mg capsule [30] (&) estradiol 0.06% (750 microgram/actuation) gel [64 actuations], 1 pack) (Estrogel Pro®) are now listed on the PBS for menopausal hormone therapy. Estradiol, progesterone and progesterone (&) estradiol are each listed as an unrestricted benefit.

Estradiol (100 microgram/24 hours patch, 24) (Estramon (Germany, Sandoz)®) for menopausal hormone therapy is now on the PBS for the current supply shortage under Section 19A. Estradiol is listed as an unrestricted benefit.

Estradiol + norethisterone acetate (estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch (ESTALIS 140/50 (Canada) ®); estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch (ESTALIS 250/50 (Canada)®) for menopausal hormone therapy is now on the PBS for the current supply shortage under Section 19A. Estradiol + norethisterone is listed as an unrestricted benefit and a restricted benefit for 60 day dispensing.

Diabetes mellitus type 2

Acarbose (50 mg tablet; 100 mg tablet) (acarbose 50 mg tablets (Morningside, UK)®; acarbose 100 mg tablets (Morningside, UK)®) for the treatment of diabetes mellitus type 2 is now listed on the PBS for the current supply shortage under Section 19A. Acarbose is listed as an unrestricted benefit and a restricted benefit for 60 day dispensing.

1 March 2025 delisted PBS listings

Migraine

Sumatriptan (20 mg/actuation nasal spray, 2 x 1 actuation) (Imigran®) has been delisted.

PBS Authorities – Changes from 1 March 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 March 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 moderate to severe hidradenitis suppurativa

Authority applications for initial and continuing treatment with adalimumab and secukinumab and authority applications for grandfather treatment with secukinumab can now be made either using the Online PBS Authorities system or in writing.

Important Information

Submitting Pharmaceutical Benefits Scheme (PBS) Written Applications through Health Professional Online Services (HPOS) form upload

When submitting PBS authority forms through HPOS form upload, it is important to remember that only yourself or your delegate/s are authorities to do this. Make sure you've:

- linked your prescriber number to your Provider Digital Access (PRODA) account for HPOS; and
- Set up your delegations in HPOS.

Visit servicesaustralia.gov.au/HPOS for more information on how to Link your Health Identifiers to HPOS and Manage delegations.

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.