Pharmaceutical Benefits Scheme (PBS) Listings 1 November 2024

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

Pre-symptomatic spinal muscular atrophy (SMA)
Risdiplam (Evrysdi®) (750 microgram/mL powder for oral liquid, 80 mL) is now listed on the PBS for the treatment of pre-symptomatic SMA with 3 copies of the survival motor neuron 2 (SMN2) gene. Authority applications for initial treatment can 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.

Severe established osteoporosis
Romosozumab (Evenity®) (105 mg/1.17 mL injection, 2 x 1.17 mL syringes) is now listed on the PBS for the treatment of severe established osteoporosis as first-line therapy. Authority applications for initial, grandfather and continuing treatments can be made either in real-time using the Online PBS Authorities system or by telephone. Flow-on changes have been applied to item code 12301K for consistency:

- Treatment phases have been updated to “Initial treatment – Second-line therapy" and “Continuing treatment – Second-line therapy".
- The clinical criteria “The treatment must not exceed a lifetime maximum of 12 months therapy" has been updated to “The treatment must not exceed a lifetime maximum of 12 months of PBS and non-PBS-subsidised therapy".

Mycosis fungoides cutaneous T-cell lymphoma
Chlormethine (Ledaga®) (0.016% (160 microgram/g) gel, 60 g) is now listed on the PBS for the treatment of mycosis fungoides cutaneous T-cell lymphoma. Authority applications for initial and continuing treatments can be made either in real-time using the Online PBS Authorities system or by telephone.

Severe pain, cancer pain, severe disabling pain
Morphine (Anamorph®) (morphine sulfate pentahydrate 30 mg tablet) is now listed on the PBS for the treatment of severe pain, cancer pain, and severe disabling pain. Authority applications for severe disabling pain in palliative care treatment can be made either in real-time using the Online PBS Authorities system or by telephone. For the treatment of severe pain and cancer pain, it is listed as a restricted benefit.

Diabetes mellitus type 2
Dapagliflozin + sitagliptin (Sidapvia 10/100®) (dapagliflozin 10 mg + sitagliptin 100 mg tablet, 28) is now listed on the PBS for the treatment of diabetes mellitus type 2. Prescriptions for treatment are Authority required (STREAMLINED).

Acromegaly; Functional carcinoid tumour; Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)
Lanreotide (Mytolac®)(Somatuline Autogel®) (60 mg/0.5 mL injection, 0.5 mL syringe; 90 mg/0.5 mL injection, 0.5 mL syringe; 120 mg/0.5 mL injection, 0.5 mL syringe) has had an amendment to the restriction to allow the initiation of treatment under S100 HSD Community Access arrangements. Prescriptions for initial and continuing treatments are Authority required (STREAMLINED).

Stage IV (metastatic) Merkel Cell Carcinoma
Avelumab (Bavencio®) (200 mg/10 mL injection, 10 mL vial) has had an amendment to the clinical criteria to align with the dosing recommendations in the Product Information. Prescriptions for initial and continuing treatments are Authority required (STREAMLINED).

Treatment-resistant migraine; chronic migraine
Fremanezumab (Ajovy®) (225 mg/1.5 mL injection, 1.5 mL syringe; 225 mg/1.5 mL injection, 1.5 mL pen device) for the treatment of treatment-resistant migraine & galcanezumab (Emgality®) (120 mg/mL injection, 1 mL pen device) for the treatment of chronic migraine have had an amendment to the treatment criteria for initial treatment. Prescriptions for initial and continuing treatments are Authority required (STREAMLINED).

Phenylketonuria
Glycomacropeptide formula with amino acids and low phenylalanine (PKU GMPro MIX-IN®) (powder for oral liquid, 30 x 12.5 g sachets) is now listed on the PBS for the treatment of phenylketonuria. It is listed as a restricted benefit.

Glycomacropeptide formula with amino acids, vitamins, minerals, trace elements, carbohydrate, fat and low phenylalanine (PKU GMPro ULTRA®) (powder for oral liquid, 30 x 33.4 g sachets) is now listed on the PBS for the treatment of phenylketonuria. It is listed as a restricted benefit.

Climacteric symptoms after natural or surgical menopause
Estradiol (Sandrena®) (0.1% (1 mg/g) gel, 28 x 500 mg sachets) is now listed as an unrestricted benefit.

Chemotherapy and inflammatory conditions
Methotrexate (Methoblastin®) (10 mg tablet) 10 tablet pack size is now listed on the PBS for the treatment of chemotherapy and inflammatory conditions. It is listed as an unrestricted benefit.

Hypercholesterolaemia
Ezetimibe and ezetimibe+statin fixed dose combination listings (various brands) have had amendments to the restriction level from Authority required (STREAMLINED) to unrestricted benefit, and 60 Day Prescription items have been amended to restricted benefit.

Menopausal Hormone Therapy
Estradiol (Estramon (Germany)®) (37.5 microgram/24 hours patch, 24; 50 microgram/24 hours patch, 24; 75 microgram/24 hours patch, 24; 100 microgram/24 hours patch, 24) is now listed on the PBS for the current supply shortage under Section 19A. It is listed as an unrestricted benefit.

Assisted Reproductive Technology; infertility indications other than that of Assisted Reproductive Technology
Choriogonadotropin alfa (Ovidrel (USA)®) (250 microgram/0.5 mL injection, 0.5 mL syringe) is now listed on the PBS for the current supply shortage under Section 19A. It is listed as an Authority required (STREAMLINED) benefit for Assisted Reproductive Technology, and as a restricted benefit for infertility indications other than that of Assisted Reproductive Technology.

Elevated intraocular pressure
Timolol (Timolol (Brown & Burk, UK)®) (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.

1 November 2024 delisted PBS listings

Chronic hepatitis C infection
Ribavirin (Ibavyr®) (200 mg tablet) has been delisted from the PBS with no supply only arrangement.

PBS Authorities – Changes from 1 November 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 November 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.

Treatment of spinal muscular atrophy:

- Nusinersen & risdiplam: Authority applications for initial treatment can now be made either using the Online PBS Authorities system or in writing. Authority applications for continuing or change of treatment can be made either in real-time using the Online PBS Authorities system or by telephone.
- Onasemnogene abeparvovec: Authority applications for treatment can now be made either using the Online PBS Authorities system or in writing.

Reminders

PBS Authorities – written authority application forms
It is important to note, that as of 1 November 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 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.