

# Pharmaceutical Benefits Scheme (PBS) Listings

## 1 December 2024

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

Vedolizumab (Entyvio®) (300 mg injection) is now listed on the PBS for the treatment of moderate to severe chronic pouchitis. Authority applications for initial, recommencement 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.

### **Severe Crohn's disease**

Upadacitinib (Rinvoq®) (15 mg tablet; 30 mg tablet; 45 mg tablet) for the treatment of severe Crohn's disease has had an amendment to remove the grandfather restriction. Authority applications for initial and continuing treatments can be made in writing.

### **Acute myeloid leukaemia (AML)**

Daunorubicin + cytarabine (Vyxeos®) (daunorubicin hydrochloride 44 mg + cytarabine 100 mg injection) is now listed under the Efficient Funding of Chemotherapy (EFC) Program on the PBS, instead of the Highly Specialised Drugs (HSD) Program, for the treatment of AML. Authority applications for induction therapy and consolidation therapy can be made either in real-time using the Online PBS Authorities system or by telephone.

### **Androgen deficiency; micropenis; pubertal induction; constitutional delay of growth or puberty**

Testosterone (AndroForte® 5) (testosterone 5% (50 mg/mL) cream, 50 mL) has had a change to the restrictions to allow for non-scrotal application. Authority applications can be made either in real-time using the Online PBS Authorities system or by telephone.

### **Attention deficit hyperactivity disorder**

Lisdexamfetamine (Vyvanse®) and methylphenidate (Concerta®; METHYLPHENIDATE-TEVA XR®; Methylphenidate XR ARX®; Ritalin LA®; Rubifen LA®) have had updates to the restrictions. Authority applications can be made either in real-time using the Online PBS Authorities system or by telephone.

### **Von Hippel-Lindau (VHL) disease**

Belzutifan (Welireg®) (40 mg tablet) is now listed on the PBS for the treatment of Von Hippel-Lindau (VHL) disease. Authority applications for initial, recommencing, grandfather and continuing treatments can be made either in real-time using the Online PBS Authorities system or by telephone.

### **Unresectable Stage III or Stage IV malignant melanoma**

Nivolumab + relatlimab (Opdualag®) (nivolumab 240 mg/20 mL + relatlimab 80 mg/20 mL injection, 20 mL vial) is now listed under the Efficient Funding of Chemotherapy (EFC) Program on the PBS, instead of the Highly Specialised Drugs (HSD) Program, for the treatment of unresectable Stage III or Stage IV malignant melanoma. Prescriptions for treatment are Authority required (STREAMLINED).

### **Endometriosis**

Dienogest (Visanne®) (2 mg tablet) is now listed on the PBS for the treatment of endometriosis. Prescriptions for treatment are Authority required (STREAMLINED).

### **Epilepsy; Palliative care**

Clonazepam (Clonazepam USP (Advagen Pharma, USA)®) (2 mg tablet) for the treatment of epilepsy and for palliative care is now listed on the PBS for the current supply shortage under Section 19A. Authority applications for the treatment of epilepsy can be made either in real-time using the Online PBS Authorities system or by telephone. Clonazepam is listed as a restricted benefit for use in patients receiving palliative care.

## **Hypercholesterolaemia**

Ezetimibe (Ezetimibe USP (Camber, USA)®) (10 mg tablet) for the treatment of hypercholesterolaemia is now listed on the PBS for the current supply shortage under Section 19A. Ezetimibe is listed as an unrestricted and restricted benefit.

## **1 December 2024 delisted PBS listings**

### **Relapsed and/or refractory multiple myeloma**

Elotuzumab (Empliciti®) (300 mg injection; 400 mg injection) has had its initial item code delisted from the PBS with no supply only arrangement. Continuing treatment with elotuzumab is only available through the PBS for existing eligible patients from 1 December 2024.

### **Severe dry eye syndrome**

Carmellose sodium (Refresh Liquigel®) (1% eye drops, 15 mL) has been delisted from the PBS with a 2 month supply only arrangement.

Carmellose sodium (Refresh Tears Plus®) (0.5% eye drops, 15 mL) has been delisted from the PBS with a 2 month supply only arrangement.

Carmellose sodium + glycerol (Optive®) (carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL) has been delisted from the PBS with a 2 month supply only arrangement.

### **Febrile neutropenia**

Cefepime (Cefepime Kabi®) (1 g & 2 g injection) has been delisted from the PBS with no supply only arrangement.

### **Familial homozygous hypercholesterolaemia; familial heterozygous hypercholesterolaemia; non-familial hypercholesterolaemia**

Evolocumab (Repatha®) (420 mg/3.5 mL injection, 3.5 mL cartridge) has been delisted from the PBS with a 6 month supply only arrangement.

## **PBS Authorities – Changes from 1 December 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 December 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 paroxysmal nocturnal haemoglobinuria:

- Authority applications for eculizumab, pegcetacoplan & ravulizumab for initial, grandfather and continuing treatments can now be made either using the Online PBS Authorities system or in writing.

## **Reminders**

### **Correct selection of medication**

When requesting an authority via the Online PBS Authorities system select the correct medication 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.

### **PBS Communications Survey**

We will be circulating a survey shortly, seeking input from you on our communication messages and any advice/feedback you may have.

### **More information**

For more information about the Online PBS Authorities system visit [www.servicesaustralia.gov.au/hppbsauthorities](http://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](http://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.