## Pharmaceutical Benefits Scheme (PBS) Listings 1 April 2025

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

Please note, the authority application forms that are updated as part of PBS listings changes in April and May 2025 will have the title fields in the prescriber and patient details removed. All remaining forms will be updated on 1 June 2025.

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 (40 mg/0.4 mL injection, 2 x 0.4 mL syringes) (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.

#### Vision threatening non-infectious uveitis

Adalimumab (20 mg/0.4 mL injection, 0.4 mL syringe) (Abrilada®; Amgevita®) is a new strength of biosimilar now listed on the PBS for the treatment of vision-threatening non-infectious uveitis.

## **Neuromyelitis optica spectrum disorder (NMOSD)**

Ravulizumab (300 mg/3 mL injection, 3 mL vial; 1.1 g/11 mL injection, 11 mL vial) (Ultomiris®) is now listed on the PBS for the treatment of NMOSD. Authority applications for initial and grandfather treatments can be made either in real-time 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.

## Paediatric low grade glioma and paediatric high grade glioma

Dabrafenib (50 mg capsule; 75 mg capsule; 10 mg dispersible tablet) (Tafinlar®) and trametinib (500 microgram tablet; 2 mg tablet; 50 microgram/mL powder for oral liquid, 90 mL) (Mekinist®) are now listed on the PBS for the treatment of paediatric low grade glioma and paediatric high grade glioma. Authority applications for initial, grandfather and continuing treatments can be made either in real-time using the Online PBS Authorities system or by telephone.

## High risk and intermediate-2 risk myelofibrosis and intermediate-1 risk myelofibrosis

Momelotinib (100 mg tablet; 150 mg tablet; 200 mg tablet) (Omjjara®) is now listed on the PBS for the treatment of high risk and intermediate-2 risk myelofibrosis and intermediate-1 risk myelofibrosis. 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).

Ruxolitinib (5 mg tablet; 10 mg tablet; 15 mg tablet, 20 mg tablet) (Jakavi®) has had an amendment to the restriction level. Prescriptions for initial treatment can now be made either in real-time using the Online PBS Authorities system or by telephone. Prescriptions for continuing treatment are now Authority required (STREAMLINED).

#### Diabetes mellitus type 2

Empagliflozin (10 mg tablet; 25 mg tablet) (Jardiance®) and empagliflozin + metformin (empagliflozin 5 mg + metformin hydrochloride 1 g tablet (Jardiamet 5 mg/1000 mg®); empagliflozin 5 mg + metformin hydrochloride 500 mg tablet (Jardiamet 5 mg/500 mg®); empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet (Jardiamet 12.5 mg/1000 mg®); empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet (Jardiamet 12.5 mg/500 mg®)) have an expanded listing to include add-on therapy to metformin for patients with diabetes mellitus type 2 and established cardiovascular disease, those at high risk of a cardiovascular event or patients that identify as Aboriginal or Torres Strait Islander. Prescriptions for treatment are Authority required (STREAMLINED).

## Stimulation of follicular development

Follitropin alfa + lutropin alfa (follitropin alfa 900 units (65.52 microgram)/1.44 mL + lutropin alfa 450 units/1.44 mL injection, 1.44 mL pen device) (Pergoveris®) has had a change to the restriction. Prescriptions for treatment are Authority required (STREAMLINED).

## Advanced or metastatic gastro-oesophageal cancer

Tislelizumab (100 mg/10 mL injection, 10 mL vial) (Tevimbra®) is now listed on the PBS for the treatment of advanced or metastatic gastro-oesophageal cancer. Prescriptions for treatment are Authority required (STREAMLINED).

#### Phenylketonuria

Amino acid formula with fat, carbohydrate, vitamins and minerals without phenylalanine (tablet: modified release, 6 x 100 g) (PKU Easy Microtabs Plus®) has had a change in formulation. It is listed as a restricted benefit.

## Proven glutaric aciduria type 1 and pyridoxine dependent epilepsy

Amino acid formula with vitamins and minerals without lysine and low in tryptophan (5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets) (GA explore5™) has had a change in formulation. It is listed as a restricted benefit.

## Methylmalonic acidaemia and propionic acidaemia

Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine (5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets) (MMA/PA explore5™) has had a change in formulation. It is listed as a restricted benefit.

#### Severe dry eye syndrome

Propylene glycol (0.6% eye drops, 10 mL) (Systane Balance®) is now listed on the PBS for the treatment of severe dry eye syndrome. Propylene glycol is listed as a restricted benefit.

#### 1 April 2025 delisted PBS listings

## **Chronic arthropathies (including osteoarthritis)**

Ketoprofen (200 mg modified release capsule) (Orudis SR 200®) and piroxicam (20 mg dispersible tablet) (Feldene-D®) have been delisted.

## Relief of pain and fever - for a patient identifying as Aboriginal or Torres Strait Islander

Paracetamol (24 mg/mL oral liquid, 100 mL) (Panamax®) has been delisted.

## Hypertension

Ramipril + felodipine (ramipril 2.5 mg + felodipine 2.5 mg modified release tablet) (Triasyn 2.5/2.5®) has been delisted.

## Severe dry eye syndrome

Carmellose sodium (0.5% eye drops,  $30 \times 0.4 \text{ mL}$  ampoules) (Cellufresh®) and carmellose sodium (1% eye drops,  $30 \times 0.4 \text{ mL}$  ampoules) (Celluvisc®) have been delisted.

#### Proctitis and ulcerative colitis

Hydrocortisone acetate (10% enema, 21.1 g) (Colifoam®) has been delisted.

#### **Advanced breast cancer**

Medroxyprogesterone acetate (500 mg tablet) (Provera®) has been delisted.

#### PBS Authorities - Changes from 1 April 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 April 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 ulcerative colitis

Authority applications for initial treatment with adalimumab, etrasimod, golimumab, infliximab, ozanimod, tofacitinib, upadacitinib, ustekinumab and vedolizumab, and grandfather treatment (etrasimod only) 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.

## **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 authorised 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

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.

## **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 services australia.gov.au/hpwrittenauthoritydrugs on the Services Australia website to find the most up to date authority application form for each drug, program or condition.