Please find below information relating to new and amended Pharmaceutical Benefits Scheme (PBS) listings implemented on **1 June 2024**. Frequently Asked Questions (FAQs) relating to access and use of the Online PBS Authorities system are also attached. This information may be of interest to your members.

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 hidradenitis suppurativa
Secukinumab (Cosentyx®) (150 mg/mL injection, 2 x 1 mL pen devices) is now listed on the PBS for the treatment of moderate to severe hidradenitis suppurativa. Authority applications for initial, continuing and grandfather treatments can be made in writing.

Cystic fibrosis
Ivacaftor (Kalydeco®) (25 mg granules; 50 mg granules; 75 mg granules; 150 mg tablet) has had a change in restriction to extend treatment to patients with cystic fibrosis aged 4 months and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor. Authority applications for initial and continuing treatments can be made in writing.

Moderate to severe ulcerative colitis
Ozanimod (Zeposia®) (920 mcg capsule) has had an amendment to remove the grandfather restriction. Authority applications for initial treatment 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.

Upadacitinib (Rinvoq®) (15 mg tablet; 30 mg tablet) has had an amendment to remove the grandfather restriction. Authority applications for initial treatment 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.

Ustekinumab (Stelara®) (90 mg/mL injection, 1 mL syringe) has had an amendment to remove the grandfather restriction. Authority applications for initial treatment 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.

Chronic rhinosinusitis with nasal polyps (CRSwNP)
Mepolizumab (Nucala®) (100 mg/mL injection, 1 mL pen device) has had an amendment to remove the grandfather restriction. Authority applications for initial treatment 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.

Chronic thromboembolic pulmonary hypertension (CTEPH)
Riociguat (Adempas®) (500 mcg tablet, 1 mg tablet, 1.5 mg tablet, 2 mg tablet, 2.5 mg tablet) has had a change in authority level for initial and continuing treatment for the treatment of CTEPH. Authority applications for initial treatment can made either in writing or in real-time using the Online PBS Authorities system. Authority applications for continuing treatment can be made either in real-time using the Online PBS Authorities system or by telephone.

Familial heterozygous hypercholesterolaemia & non-familial hypercholesterolaemia
Inclisiran (Leqvio®) (284 mg/1.5 mL injection, 1.5 mL prefilled syringe) has had a change to the restrictions for the treatment of familial heterozygous hypercholesterolaemia & non-familial hypercholesterolaemia. Authority applications for initial and grandfather treatments

can be made either in real-time using the Online PBS Authorities system or by telephone. Prescriptions for continuing treatment are Authority Required (STREAMLINED).

Stage IB, II or IIIA non-small cell lung cancer (NSCLC)
Osimertinib (Tagrisso®) (40 mg tablet; 80 mg tablet) is now listed on the PBS for the treatment of Stage IB, II or IIIA NSCLC. Authority applications for initial, grandfather and continuing treatments can be made either in real-time using the Online PBS Authorities system or by telephone.

Achondroplasia
Vosoritide (Voxzogo®) (400 mcg injection; 560 mcg injection; 1.2 mg injection) has had an amendment to remove the grandfather restriction. Authority applications can be made either in real-time using the Online PBS Authorities system or by telephone.

Diabetes mellitus type 2
Dulaglutide (Trulicity®) (1.5 mg/0.5 mL injection, 4 x 0.5 mL pen devices) and semaglutide (Ozempic®) (1.34 mg/mL injection, 1 x 1.5 mL pen device; 1 x 3 mL pen device) have had a change in authority level for initial treatment of diabetes mellitus type 2. 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).

There are restriction changes to medicines used to treat diabetes mellitus type 2, including empagliflozin, dapagliflozin, alogliptin, saxagliptin, sitagliptin, linagliptin, and vildagliptin. Prescriptions for treatment are Authority Required (STREAMLINED).

Pioglitazone (Acpio 15®; Acpio 30®; Acpio 45®; Actaze®; Actos®; APOTEX-Pioglitazone®; Vexazone®) (15 mg tablet, 30 mg tablet, 45 mg tablet) has had a change to the authority level for the treatment of diabetes mellitus type 2. It is now listed as a restricted benefit.

Asthma & chronic obstructive pulmonary disease (COPD)
Budesonide + formoterol (Bufomix Easyhaler®) (budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations; budesonide 400 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations) is now listed on the PBS for the treatment of asthma & COPD. Prescriptions for initial and continuing treatments are Authority Required (STREAMLINED).

Severe established osteoporosis
Teriparatide (Terrosa®) (250 microgram/mL injection, 2.4 mL cartridge) has had a decrease to the number of repeats for the continuing treatment of severe established osteoporosis. Prescriptions for initial and continuing treatments are Authority Required (STREAMLINED).

Grade II to IV acute graft versus host disease (aGVHD) & moderate to severe chronic graft versus host disease (cGVHD)
Ruxolitinib (Jakavi®) (5 mg tablet; 10 mg tablet) has had an amendment to remove the grandfather restriction. Prescriptions for initial and continuing treatments are Authority Required (STREAMLINED).

Stage IV clear cell variant renal cell carcinoma
Lenvatinib (Lenvima®) (4 mg capsule; 10 mg capsule) has had an amendment to remove the grandfather restriction. Prescriptions for initial and continuing treatments are Authority Required (STREAMLINED).

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

Unresectable Stage III or Stage IV malignant melanoma
Nivolumab (Opdivo®) (40 mg/4 mL injection, 4 mL vial; 100 mg/10 mL injection, 10 mL vial) has had an amendment to remove the grandfather restriction. Prescriptions for initial and continuing treatments are Authority Required (STREAMLINED).

Severe chronic plaque psoriasis
Apremilast (Otezla®) (30 mg tablet; pack containing apremilast 10 mg tablet [4] (&) apremilast 20 mg tablet [4] (&) apremilast 30 mg tablet [19], 27) has had a change to allow treatment initiation by additional medical practitioner types. Prescriptions for initial and continuing treatments are Authority Required (STREAMLINED).

Contraception, endometriosis & carcinoma
Medroxyprogesterone acetate (Depo-Provera®) (150 mg/mL injection, 1 mL syringe) is now listed for the treatment of contraception, endometriosis and carcinoma. Medroxyprogesterone acetate is listed as an unrestricted benefit.

Menopausal hormone therapy
Estradiol (Estradiol Transdermal System®) (100 mcg/24 hours patch; 75 mcg/24 hours patch; 37.5 mcg/24 hours patch) for menopausal hormone therapy is now listed on the PBS for the current supply shortage under Section 19A. Estradiol is listed as an unrestricted benefit.

Treatment of infections
Benzathine benzylpenicillin (Extencilline Benzathine Benzylpenicillin (France)®) (1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial]) for the treatment of infections is now listed on the PBS for the current supply shortage under Section 19A. Benzathine benzylpenicillin is listed as an unrestricted benefit.

1 June 2024 delisted PBS listings

For the treatment of constipation, anorectal congenital abnormalities, terminal malignant neoplasia and megacolon
Bisacodyl (Bisalax®) (10 mg/5 mL enema, 25 x 5 mL) has been delisted from the PBS with a 3 month supply only arrangement.

For the treatment of fungal or yeast infection
Ketoconazole (Nizoral 2% Cream®) (2% cream, 30 g) has been delisted from the PBS with a 3 month supply only arrangement.

OPA Milestone reached!!

In early May, the Online PBS Authorities (OPA) System reached a milestone of 2 million authority approval requests in this financial year requested by over 17,000 individual prescribers. Services Australia is listening to prescribers' feedback and continue to improve the functionality in the OPA system. Users will see changes from July 2024.

Changes to the prescription process from 1 July 2024

The Department of Health and Aged Care has reviewed and remade the following instruments: the *National Health (Listings of Pharmaceutical Benefits) Instrument 2012*, the *National Health (Prescriber bag supplies) Determination 2012*, and the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011*. As a result of the review, the *National Health (Pharmaceutical Benefits) Regulations 2017* have also been amended. For further information regarding the legislation changes go to www.legislation.gov.au.

The remade legislation took effect on 1 April 2024 and changed Services Australia's processes for PBS Authority Required applications submitted via the post. We no longer require the original prescription to assess your request, only the details of the proposed PBS

prescription. We won't record the Authority Approval Number on the prescription or forward approved prescriptions to the patient.

A transition period will be in place from 1 April 2024, with the process changes coming into full effect on 1 July 2024.

From 1 July 2024, Services Australia will only accept details of the proposed PBS prescription (and PDF form where appropriate) when seeking PBS authority approval via the post.

Once processed, the assessment outcome will be sent to the prescriber via the post. If approved, the prescriber will need to endorse the original PBS authority prescription with the PBS Approval Number and PBS item code.

It's important to note all original prescriptions received via the post that are written on or after 1 July 2024 will be immediately returned to the prescriber. Services Australia will retain a copy of the prescription for processing.

We're updating PBS Authority prescription pads to remove the 'Tick for return to patient' checkbox. You can continue to use your residual stock as it will still be valid.

We understand having timely access to PBS-subsidised medicines can be critical to patient care. You can submit written PBS Authorities through the Health Professional Online Services (HPOS) Form Upload function. Also, most PBS Authorities can be requested and approved in 'real time' using the Online PBS Authorities system.

For more information about HPOS Form Upload visit **www.servicesaustralia.gov.au/hpos**

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. For more information go to **servicesaustralia.gov.au/hpos**

*Received from **Services Australia***