



**Australian Government**

**Department of Health**

## **Information for Healthcare Professionals and Patients**

### **Dual Therapy PBS listings for Pulmonary Arterial Hypertension Medicines**

In November 2018, the Pharmaceutical Benefits Advisory Committee (PBAC) considered the Post-market Review of Pulmonary Arterial Hypertension (PAH) medicines. Consequently, the PBAC recommended changes to individual listings of PBS-subsidised PAH medicines. Further details are available from the PBAC outcome statements for the November 2018, March 2019 and November 2019 PBAC meetings.

At the November 2019 meeting, the PBAC recommended extending access to PAH medicines from the endothelin receptor antagonist (ERA) and phosphodiesterase-5 inhibitor (PDE-5i) classes for patients with World Health Organisation (WHO) Functional Class (FC) III and IV symptoms.

From 1 October 2020, the following PBS subsidised PAH medicines will be available to PAH patients with WHO FC III and IV symptoms for ERA-PDE-5i dual therapy:

- ERA medicines: bosentan, macitentan
- PDE-5i medicines: sildenafil, tadalafil

Refer to the Schedule of Pharmaceutical Benefits, available online, in PDF and in prescribing software, for detailed information on the PBS prescribing restrictions.

#### **What does this change mean for prescribers?**

Effective 1 October 2020, a summary of restriction phases for PBS subsidised ERA and PDE-5i PAH medicines (DUAL THERAPY) is shown in the table below.

<b>Treatment Phase/ Restriction</b>	<b>Level of Authority</b>	<b>Test Requirements</b>	<b>Supporting Documentation</b>
Initial 1 (new patients)	Written	<ul style="list-style-type: none"><li>• Right Heart Catheterisation (RHC)</li><li>• Echocardiogram</li><li>• Six Minute Walk Test</li></ul> OR <ul style="list-style-type: none"><li>• preferred combination</li></ul> Exemptions from the RHC require reconfirmation from a second expert cardiologist or PAH physician	<ul style="list-style-type: none"><li>• completed authority prescription form; and</li><li>• a completed PAH PBS Authority Application - Supporting Information form</li></ul>

Treatment Phase/ Restriction	Level of Authority	Test Requirements	Supporting Documentation
Initial 2 (previously treated patients)	Telephone/Electronic	Results and date of previous tests as applicable must be included in the patient's medical record.  Exemptions from the RHC require reconfirmation from a second expert cardiologist or PAH physician for inclusion in the patient's record.	<ul style="list-style-type: none"> <li>completed authority prescription form</li> </ul>
Initial 3 (change)	Telephone /Electronic	Nil	<ul style="list-style-type: none"> <li>completed authority prescription form</li> </ul>
Grandfathered patients	Written	<ul style="list-style-type: none"> <li>Right Heart Catheterisation (RHC)</li> <li>Echocardiogram</li> <li>Six Minute Walk Test</li> <li>OR</li> <li>preferred combination</li> </ul> Exemptions from the RHC require reconfirmation from a second expert cardiologist or PAH physician	<ul style="list-style-type: none"> <li>completed authority prescription form; and</li> <li>a completed PAH PBS Authority Application - Supporting Information form</li> </ul>
Continuing treatment	Telephone / Electronic	Nil	<ul style="list-style-type: none"> <li>completed authority prescription form</li> </ul>
Bosentan 62.5mg only: Cessation of treatment (all patients)	Telephone / Electronic	Nil	<ul style="list-style-type: none"> <li>completed authority prescription form</li> </ul>

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the [Services Australia website](#).

For written Authority applications,

- upload through HPOS
- post to:  
Services Australia  
Complex Drugs Programs  
Reply Paid 9826  
HOBART TAS 7001
- for more information, contact Services Australia on 1800 700 270 Monday to Friday, 8 am to 5 pm AEST

For telephone authority applications

- Phone: 1800 700 270 Monday to Friday, 8 am to 5 pm AEST

For electronic authority applications,

- real-time authority approval can be requested through the [Online PBS Authorities system \(OPA\)](#)

For more information about the prescribing, dispensing or claiming of PBS drugs, please call Services Australia on 132290 or visit the [Services Australia website](#) or the [PBS website](#).

General questions about the PBS should be directed to the PBS general enquiry line on 1800 020 613 or email to [pbs@health.gov.au](mailto:pbs@health.gov.au).

### **What does this change mean for pharmacists?**

From 1 October 2020, there will be new PBS item codes for these ERA and PDE-5i PAH medicines for dual therapy.

Pharmacists are required to ensure that prescriptions have a valid Authority approval prior to dispensing. If a pharmacist is presented with an authority PBS prescription and is not sure if it has been approved, he or she should contact Services Australia. Please note that Services Australia will not provide clinical information.