

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to [Section H](#) of the Pharmaceutical Schedule. For community funding, see the [Special Authority Criteria](#).

PRESCRIBER

Name:

Ward:

PATIENT:

Name:

NHI:

Bosentan

INITIATION – PAH monotherapy

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- Prescribed by, or recommended by a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- Patient has pulmonary arterial hypertension (PAH)*

and

- PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications

and

- PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV

and

- PAH has been confirmed by right heart catheterisation

and

- A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair)

and

- A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg

and

- Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm⁻⁵)

and

- PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH

or

- Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**

or

- Patient has PAH other than idiopathic / heritable or drug-associated type

or

- Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease

or

- Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures

and

- Bosentan is to be used as PAH monotherapy

and

- Patient has experienced intolerable side effects on sildenafil

or

- Patient has an absolute contraindication to sildenafil

or

- Patient is a child with idiopathic PAH or PAH secondary to congenital heart disease

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PRESCRIBER

PATIENT:

Name:

Ward: NHI:

Bosentan - continued

INITIATION – PAH dual therapy

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- Prescribed by, or recommended by a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- Patient has pulmonary arterial hypertension (PAH)*

and

- PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications

and

- PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV

and

- PAH has been confirmed by right heart catheterisation

and

- A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair)

and

- A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg

and

- Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm⁻⁵)

and

- PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH

or

- Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**

or

- Patient has PAH other than idiopathic / heritable or drug-associated type

or

- Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease

or

- Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures

and

- Bosentan is to be used as part of PAH dual therapy

and

- Patient has tried a PAH monotherapy (sildenafil) for at least three months and has experienced an inadequate therapeutic response to treatment according to a validated risk stratification tool**

or

- Patient is presenting in NYHA/WHO functional class III or IV, and in the opinion of the treating clinician would likely benefit from initial dual therapy

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PRESCRIBER

PATIENT:

Name:

Ward: NHI:

Bosentan - continued

INITIATION – PAH triple therapy

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- Prescribed by, or recommended by a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- Patient has pulmonary arterial hypertension (PAH)*

and

- PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications

and

- PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV

and

- PAH has been confirmed by right heart catheterisation
- and
- A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair)
- and
- A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
- and
- Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm⁻⁵)

- PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH
- or
- Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**
- or
- Patient has PAH other than idiopathic / heritable or drug-associated type

or

- Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease

or

- Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures

and

- Bosentan is to be used as part of PAH triple therapy

and

- Patient is on the lung transplant list

or

- Patient is presenting in NYHA/WHO functional class IV

or

- Patient has tried PAH dual therapy for at least three months and has not experienced an acceptable response to treatment according to a validated risk stratification tool**

and

- Patient does not have major life-threatening comorbidities and triple therapy is not being used in a palliative scenario

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PRESCRIBER

PATIENT:

Name:

Name:

Ward:

NHI:

Bosentan - *continued*

CONTINUATION

Re-assessment required after 2 years

Prerequisites (tick box where appropriate)

Prescribed by, or recommended by a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

Patient is continuing to derive benefit from bosentan treatment according to a validated PAH risk stratification tool**

Note: ** the requirement to use a validated risk stratification tool to determine insufficient response applies to adults. Determining insufficient response in children does not require use of a validated PAH risk stratification tool, where currently no such validated tools exist for PAH risk stratification in children.

I confirm that the above details are correct:

Signed: Date: