HOSPITAL MEDICINES LIST
RESTRICTIONS CHECKLIST

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 (see note below for link to these guidelines) †

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

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

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 (see note below for link to these guidelines) †

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

Name: .....

Ward: .....

PATIENT:

Name: .....

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})

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 (see note below for link to these guidelines) †

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

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

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 European Respiratory Journal Guidelines can be found here: 2022 ECS/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension PAH
** 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: .....