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: .....

Ambrisentan

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 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

- ○ Ambrisentan is to be used as PAH monotherapy

and

- ○ Patient has experienced intolerable side effects with both sildenafil and bosentan

or

- ○ Patient has an absolute contraindication to sildenafil and an absolute or relative contraindication to bosentan (e.g. due to current use of a combined oral contraceptive or liver disease)

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: .....

Ambrisentan *- 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 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

- ○ Ambrisentan is to be used as PAH dual therapy

and

- ○ Patient has tried bosentan (either as PAH monotherapy, or PAH dual therapy with sildenafil) for at least three months and has not experienced an acceptable response to treatment according to a validated risk stratification tool**

or

- ○ Patient has experienced intolerable side effects on bosentan

or

- ○ Patient has an absolute or relative contraindication to bosentan (e.g. due to current use of a combined oral contraceptive or liver disease)

or

- ○ Patient is presenting in NYHA/WHO functional class III or IV, and would benefit from initial dual therapy in the opinion of the treating clinician and has an absolute or relative contraindication to bosentan (eg. due to current liver disease or use of a combined oral contraceptive)

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ambrisentan *- 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 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

- ○ Ambrisentan is to be used as PAH triple therapy

and

- ○ Patient is on the lung transplant list

or

- ○ Patient is presenting in NYHA/WHO functional class IV

and

- ○ Patient has an absolute or relative contraindication to bosentan (e.g. due to current use of a combined oral contraceptive or liver disease)

or

- ○ Patient has tried PAH dual therapy for at least three months and remains in an unacceptable risk category 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:

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ambrisentan *- 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

- ○ The patient is continuing to derive benefit from ambrisentan 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: .....