

APPLICANT (stamp or sticker acceptable) **PATIENT NHI:** **REFERRER** Reg No:

Reg No: First Names: First Names:

Name: Surname: Surname:

Address: DOB: Address:

..... Address:

.....

Fax Number: Fax Number:

Bosentan

Initial application — PAH monotherapy

Applications only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

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

I confirm the above details are correct and that in signing this form I understand I may be audited.

Signed: Date:

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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Bosentan - continued

Initial application — PAH dual therapy

Applications only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

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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Bosentan - continued

Initial application — PAH triple therapy

Applications only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

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 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 the above details are correct and that in signing this form I understand I may be audited.

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Bosentan - continued

Renewal

Current approval Number (if known):.....

Applications only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 2 years.

Prerequisites(tick box where appropriate)

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 the above details are correct and that in signing this form I understand I may be audited.

Signed: Date:

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz