Enquiries to Ministry of Health
0800 855 066

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Form SA2254
January 2025

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

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

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

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.....	.....	.....
Fax Number:	.....	Fax Number: .....

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 (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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.....	.....	.....
Fax Number:	.....	Fax Number: .....

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 (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

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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 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.

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