

APPLICANT (stamp or sticker acceptable)	PATIENT NHI:	REFERRER Reg No:
Reg No:	First Names:	First Names:
Name:	Surname:	Surname:
Address:	DOB:	Address:
.....	Address:	
.....		
.....		

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:

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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)
or	☐	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

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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.

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