

# ELIGIBILITY CRITERIA FOR PULMONARY ARTERIAL HYPERTENSION THERAPY

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## **ELIGIBILITY CRITERIA FOR INITIATION OF PULMONARY ARTERIAL HYPERTENSION THERAPY**

These guidelines are intended to assist relevant practitioners in gauging which patients are likely to be approved for pulmonary arterial hypertension treatments. In view of the complexity of pulmonary arterial hypertension diagnosis, classification and severity assessment, each application is thoroughly evaluated by the PAH Panel to determine the appropriateness of pulmonary vasodilator treatment.

Please note that the pharmaceuticals covered by these access criteria have different registered indications, and that some of the criteria included here are Unapproved Indications. If clinicians are intending to prescribe any of these pharmaceuticals for an Unapproved Indication, they should be aware of and comply with their obligations, including those set out in rule 4.6 of the Pharmaceutical Schedule.

All requested studies should be carried out in line with the relevant professional guidelines. Patients with pulmonary arterial hypertension who meet the following criteria may be eligible for initiation of pulmonary arterial hypertension treatment based on current clinical evidence.

The following treatments may be subsidised by application to the PAH Panel:

<b>Category</b>	<b>Treatment</b>
Endothelian receptor antagonists	Bosentan (Tracleer)
Phosphodiesterase type 5 inhibitors	Sildenafil (Viagra)
Prostacyclin analogues	Iloprost (Ventavis)

# Patients eligible for initial approval of Special Authority

1. The patient must have a diagnosis of pulmonary arterial hypertension with the following WHO (Venice) clinical classifications:

- **Group 1**
  - Idiopathic;
  - Familial;
  - Associated with:
    - Connective tissue disease;
    - Congenital systemic pulmonary shunts;
    - Portal hypertension;
    - HIV infection;
    - Drugs and toxins;
    - Other;
  - Associated with significant venous or capillary involvement:
    - Pulmonary veno-occlusive disease (PVOD);
    - Pulmonary capillary haemangiomas (PCH);
  - Persistent pulmonary hypertension of the newborn (PPHN)
  
- **Group 4**
  - Pulmonary arterial hypertension due to thrombotic and/or embolic disease only)
  
- **Group 5**
  - Miscellaneous group
    - E.g. sarcoidosis, histiocytosis X and lymphangiomatosis

Patients with PAH classified as group 2 or 3 are not eligible for subsidised treatment.

- **Group 2** - pulmonary hypertension associated with left heart disease
  
- **Group 3** - pulmonary hypertension associated with respiratory diseases and / or hypoxaemia

Lung function tests and cardiac function tests must be supplied with the initial application. For children under 10 years old, funding of sildenafil monotherapy will be considered using the data provided according to the application forms for children less than 10 years.

2. The patient must have NYHA/WHO functional class III or IV. For patients who are functional class II, applications will be considered in cases where there is clear evidence of disease progression (defined as a deterioration in performance of the 6MWT or deterioration in haemodynamic variables) despite current therapy.

Patients who are functional class I are not eligible for subsidised treatment.

New York Heart Association / World Health Organization Functional Classification of Pulmonary Hypertension	
Class I:	Patients with pulmonary hypertension but without resulting limitation of physical activity. Ordinary physical activity does not cause undue dyspnoea or fatigue, chest pain, or near syncope.
Class II:	Patients with pulmonary hypertension resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity does not cause undue

	dyspnoea or fatigue, chest pain, or near syncope.
Class III:	Patients with pulmonary hypertension resulting in pronounced limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes undue dyspnoea or fatigue, chest pain, or near syncope.
Class IV:	Patients with pulmonary hypertension with inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Right cardiac catheterisation data<sup>1</sup> must be supplied with the application. If cardiac catheterisation is contra-indicated, a letter of explanation is required. Unequivocal, significant evidence of raised pulmonary arterial pressure, in the absence of significant left heart disease, must be demonstrated.

- The patient must have a pulmonary capillary wedge pressure (PCWP)  $\leq$  15 mmHg (patients with a PCWP between 15 mmHg and 18 mmHg may be considered at the Panel's discretion).
- The patient must have a mean pulmonary artery pressure (PAPm)  $>$  25 mmHg.
- An assessment of vasoreactivity has been carried out using iloprost, adenosine or nitric oxide. Where this assessment has not been carried out, applicants must provide reasons for this. (Vasoreactivity studies are not mandatory in patients with severe PAH (functional class IV or right atrial pressure  $>$  12 mmHg or Cardiac Index  $<$  2 l/min/m<sup>2</sup>) or PAH associated with connective tissue disease.)
- Where the patient has been shown to be vasoreactive (defined as a fall in mean PAP of greater than or equal to 10mmHg to less than 40mmHg with either an increase or no change in cardiac index), evidence of an adequate therapeutic trial of calcium channel blockers for three to six months must have been undertaken, followed by re-catheterisation demonstrating evidence of haemodynamic progression. (Due to the negative inotropic effects of CCBs, a trial of CCBs is not required in patients with severe disease as defined above.)

### Treatment selection

#### *Initial treatment:*

- Patients who have not previously been treated with any of these agents would generally be expected to start treatment with sildenafil.
- NYHA WHO functional class IV patients who have been stabilised in hospital on iloprost would be able to receive iloprost in the community for a period of time to allow transition to sildenafil monotherapy, if clinically appropriate.

#### *Change of treatment:*

- Where sildenafil is not tolerated due to side-effects clinicians may apply for monotherapy with either bosentan or iloprost.

<sup>1</sup> Grossman, W (Ed). Cardiac Catheterization and Angiography, 3rd ed, Lea & Febiger, Philadelphia 1986

- Where the patient has not responded to sildenafil monotherapy, clinicians may apply for alternative monotherapy within 6 months of treatment initiation.

## **Patients eligible for renewal of Special Authority**

Renewal applications must be submitted to the PAH Panel after six months of treatment approval, with annual reviews required thereafter.

### **Treatment selection**

#### *Renewal of treatment (stable patients):*

- Patients who are stable or improve on PAH therapy will be considered for renewal of special authority.

#### *Escalation of treatment:*

- Eligibility for combination therapy for patients stable on treatment for at least six months who then deteriorate shall be determined by:
  - Clear evidence of deterioration in right heart cardiac catheterisation measures; or
  - 15% deterioration in two 6MWTs done at least two weeks apart; or
  - NYHA/WHO functional class IV.
- Where patients show signs and symptoms of deterioration, and escalation of treatment is requested, a repeat right heart cardiac catheter is mandatory, except if the cardiac catheter is contraindicated, when a letter of explanation must be provided for the Panel to consider.
- Patients who have failed to respond to two monotherapies within the first six months of treatment may be eligible for combination therapy.
- Combination bosentan/iloprost may be considered for patients who cannot tolerate a sildenafil regime.
- Combination sildenafil/bosentan/iloprost therapy will not be approved.

**Initial Application for Funding of Pulmonary Arterial Hypertension Treatments  
for Adults (and children aged over 10 years)**

Date of Application \_\_\_\_\_

Please send applications to:

PAH Panel Coordinator  
PHARMAC  
P O Box 10-254  
WELLINGTON

Phone: 04 9167 512

Facsimile: 04 974 4858

Email: [PAH@pharmac.govt.nz](mailto:PAH@pharmac.govt.nz)

*Applications **must** be **complete** and accompanied by supporting data where required.*

**Have you attached:**

- Cardiac catheterisation reports
- Lung function tests
- Echocardiography report
- Vasoreactivity data
- CCB trial results

Patient Details – patient sticker is acceptable			
Surname:			
First Name/s:			
NHI No:			
Gender:	<input type="checkbox"/> Male <input type="checkbox"/> Female		
D.O.B:			
Address:			
Phone No:	Home:	Work:	Mobile:
Email:			

Physician Details	
Name:	
NZMC Registration Number:	
Practice Address:	
Phone No:	
Mobile No:	
Fax No:	
Email:	
Signature of applying physician:	



<b>Basis of request for PAH treatments</b>	
<b>Diagnosis</b>	<b>Tick</b>
Patient has been diagnosed as having pulmonary arterial hypertension	<input type="checkbox"/>
<b>NYHA/WHO functional class</b>	
*2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/>	* Note: Applications for patients with functional class 2 need to demonstrate clear evidence of disease progression on current treatments.
<b>WHO (Venice) clinical classification</b>	
<u>Group One</u> – Pulmonary arterial hypertension	
Idiopathic PAH	<input type="checkbox"/>
Familial PAH	<input type="checkbox"/>
Associated with other diseases:	
Connective tissue disease	<input type="checkbox"/>
Congenital systemic pulmonary shunts	<input type="checkbox"/>
Portal hypertension	<input type="checkbox"/>
HIV infection	<input type="checkbox"/>
Drugs/toxins	<input type="checkbox"/>
Other (specify):	<input type="checkbox"/>
Associated with significant venous or capillary involvement	
Pulmonary veno-occlusive disease	<input type="checkbox"/>
Pulmonary capillary haemangiomas	<input type="checkbox"/>
Persistent pulmonary hypertension of the newborn	<input type="checkbox"/>
<u>Group Four</u> – Pulmonary hypertension due to chronic thrombotic and/or embolic disease only	<input type="checkbox"/>
<u>Group Five</u> – Other pulmonary hypertension (specify)	<input type="checkbox"/>

Test results					
Height (cm):		Weight (kg):		BMI (kg/m <sup>2</sup> ):	
<b>Lung function</b>					
Date of test:		Please report as actual values and percent predicted and attach report			
	Actual		Percent predicted		
FEV <sub>1</sub>					
FVC					
FEV <sub>1</sub> /FVC (%)					
DLCO					
DLCO/VA					
TLC					
<b>Six minute walk test:</b>					
Date of test:					
Distance walked (m):					
SpO <sub>2</sub> :		Baseline:		Nadir:	
Heart Rate:		Baseline:		Maximum:	
Borg Index:		Pre:		Post:	
<b>Brain natriuretic peptide if available – please provide reference data</b>					

<b>Right Heart Cardiac Catheter (please attach reports)</b>		
Date of test: Testing centre:		
	<b>Pre vasoreactivity testing</b>	<b>Post vasoreactivity testing</b>
Pulmonary capillary wedge pressure: (Threshold: $\leq 15$ mmHg):		
Pulmonary artery pressures:	Mean:	
	Systolic:	
	Diastolic:	
Mean right atrial pressure:		
Pulmonary vascular resistance:	<input type="checkbox"/> Wood units	
	<input type="checkbox"/> International units	
Cardiac output:		
Cardiac index:		
<b>Vasoreactivity</b>		
Has the patient been assessed for vasoreactivity using iloprost, adenosine or nitric oxide? If no, please provide reasons:		<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Cardiac catheterisation contraindicated:</b>		
<b>Discussion:</b>		

**Calcium channel blocker (CCB) history**

- If the patient has idiopathic PAH and is vasoreactive, and has had a trial of CCBs for at least three months (preferably six), please attach re-catheterisation data demonstrating disease progression despite CCB treatment.
- If necessary, please provide discussion of CCB treatment:

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**Echocardiography (please attach full report)**

Date of test:

Echo RVP

Echo RAP

**Medical History**

Transplant status:

- Not suitable for referral/turned down
- Not yet referred
- Inactive waiting list
- Active waiting list

**Comorbidities:**

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**Current and relevant medications (including CCBs):**

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**Would you like to make any other comments in support of this application?**

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**Renewal Application / Request for Change of Therapy for Pulmonary Arterial Hypertension Treatments for Adults (and children aged over 10 years)**

Use this form for renewal applications and applications for therapy changes. Initial approval is valid for a period of six months. Subsequent approvals are valid for twelve months.

**Date of Application:** \_\_\_\_\_

**Please send applications to:**

PAH Panel Coordinator  
PHARMAC  
P O Box 10-254  
WELLINGTON

Phone: 04 9167 512

Facsimile: 04 974 4858

Email : [PAH@pharmac.govt.nz](mailto:PAH@pharmac.govt.nz)

*Applications **must be complete** and accompanied by supporting data where required.*

**Have you attached:**

- Cardiac catheterisation report
- Echo results

Patient Details – patient sticker is acceptable			
Surname:			
First Name/s:			
NHI No:			
Gender:	<input type="checkbox"/> Male <input type="checkbox"/> Female		
D.O.B:			
Address:			
Phone No:	Home:	Work:	Mobile:
Email:			

Patient's Physician	
Name:	
NZMC Registration Number:	
Practice Address:	
Phone No:	
Mobile No:	
Fax No:	
Email:	

Signature of applying physician:		Date:
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**Current treatment and dosing:**  
**Treatment requested**

Endothelien receptor antagonists [*bosentan*]

Phosphodiesterase type-5 inhibitors [*sildenafil*]

Prostacyclin analogues [*iloprost*]

Are you applying for a change in therapy?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Are you applying for combination treatment?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Are you applying for a renewal of current treatment only?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

**If applying for a change of therapy or combination therapy, please indicate reasons for change:**

Intolerance of current treatment (please provide details below)

Lack of response to current treatment (please provide details below)

Disease progression following previous disease stability (please provide details below)

Please discuss the rationale for requesting a change in treatment:

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- Note:**
- Where the patient has not responded to sildenafil monotherapy, clinicians may apply for alternative monotherapy within 6 months of treatment initiation.
  - Combination sildenafil/bosentan sildenafil/iloprost therapy may be approved after failure of monotherapy
  - Combination bosentan/iloprost therapy will not be approved, except for patients with

documented intolerance of sildenafil.

- Triple therapy (bosentan/sildenafil/iloprost) will not be approved.

Status Update					
<b>NYHA/WHO functional class</b>					
2 <input type="checkbox"/>		3 <input type="checkbox"/>		4 <input type="checkbox"/>	
Test results					
Height (cm):		Weight (kg):		BMI (kg/m <sup>2</sup> ):	
<b>Six minute walk test (x2 if annual renewal ie done every six months):</b>					
Distance walked (m):					
SpO2:		Baseline:		Nadir:	
Heart Rate:		Baseline:		Maximum:	
Borg Index:		Pre:		Post:	
<b>Brain natriuretic peptide if available – please provide reference data:</b>					

<b>Right heart cardiac catheter (please attach report)</b>		
Date of test:		
All patients: Repeat cardiac catheter reports must be provided one year after the start of treatment. <ul style="list-style-type: none"> <li>▪ Stable patients: cardiac catheter reports are required at 2 to 4 year intervals depending upon patient progress.</li> <li>▪ Unstable patients: Where escalation of treatment is requested, a repeat right heart cardiac catheter is mandatory.</li> </ul>		
Testing centre:		
Pulmonary capillary wedge pressure: (Threshold: ≤ 15 mmHg)		
Pulmonary artery pressures:	Mean:	
	Systolic:	
	Diastolic:	



**Initial Application for Funding of Pulmonary Arterial Hypertension Treatment**  
**Application for children less than 10 years for PDE-5 inhibitor (sildenafil)**  
**treatment**

This form is applicable for younger patients requiring PDE-5 inhibitor (**sildenafil**) monotherapy only. If other treatments are required use the form for adults and children aged over 10 years.

**Date of Application:** \_\_\_\_\_

**Please send applications to:**

PAH Panel Coordinator  
 PHARMAC  
 P O Box 10-254  
 WELLINGTON

Phone: 04 9167 512

Facsimile: 04 974 4858

Email: [PAH@pharmac.govt.nz](mailto:PAH@pharmac.govt.nz)

*Applications **must be complete** and accompanied by supporting data where required.*

**Have you attached:**

- Cardiac catheterisation report
- Echocardiography report
- CT report

Patient Details – patient sticker is acceptable			
Surname:			
First Name/s:			
NHI No:			
Gender:	<input type="checkbox"/> Male <input type="checkbox"/> Female		
D.O.B:			
Address:			
Phone No:	Home:	Work:	Mobile:
Email:			

Physician Details	
Name:	
NZMC Registration Number:	
Practice Address:	
Phone No:	
Mobile No:	
Fax No:	
Email:	

Signature of applying physician:	
<b>Treatment requested</b>	
<input type="checkbox"/> Phosphodiesterase type-5 inhibitors <i>[sildenafil]</i>  <input type="checkbox"/> <b>Suspension required.</b> Please indicate which suspension product will be used: <ul style="list-style-type: none"> <li><input type="checkbox"/> Methycellulose or water. Available via community funding, dispensed by HP1 community pharmacies and hospital pharmacies.</li> <li><input type="checkbox"/> Ora-Blend or Ora-Plus or Ora-Sweet. Available via DHB Hospital funding, dispensed only by hospital pharmacies. Please ensure that the funding DHB hospital has agreed to pay for this suspending product.</li> </ul>	

Please discuss the rationale for the proposed treatment regime:

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Please describe anticipated benefits of treatment

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<b>Basis of request for PAH treatments</b>	
<b>Diagnosis</b>	<b>Tick</b>
Patient has been diagnosed as having pulmonary arterial hypertension	<input type="checkbox"/>
<b>WHO (Venice) clinical classification</b>	
<u>Group One</u> – Pulmonary arterial hypertension	
Idiopathic PAH	<input type="checkbox"/>
Familial PAH	<input type="checkbox"/>
Associated with other diseases:	
Connective tissue disease	<input type="checkbox"/>
Congenital systemic pulmonary shunts	<input type="checkbox"/>
Portal hypertension	<input type="checkbox"/>
HIV infection	<input type="checkbox"/>
Drugs/toxins	<input type="checkbox"/>
Other (specify)	<input type="checkbox"/>
Associated with significant venous or capillary involvement	
Pulmonary veno-occlusive disease	<input type="checkbox"/>
Pulmonary capillary haemangiomatosis	<input type="checkbox"/>
Persistent pulmonary hypertension of the newborn	<input type="checkbox"/>
<u>Group Four</u> – Pulmonary hypertension due to chronic thrombotic and/or embolic disease only	<input type="checkbox"/>
<u>Group Five</u> – Other pulmonary hypertension (specify)	<input type="checkbox"/>

<b>Test results</b>			
Height (cm):		Weight (kg):	
Height centile:		Weight centile:	
Gestation at birth:	Birth weight (centile):		
Number of hospital admissions:			
ICU Days:			
History of ventilation:			
Current oxygen use:			
Saturations	On Room air: _____	On Oxygen at ___ Litres/min: _____	
Results of overnight oximetry:			
Chest X Ray findings:			
<b>Six minute walk test: (if relevant)</b>		Date of test:	
Distance walked (m):			
SpO2	Baseline:		Nadir:
Heart Rate	Baseline:		Maximum:
Borg Index	Pre:		Post:
<b>Other:</b>			
Brain natriuretic peptide if available – please provide reference data:			
Radiology CT Chest results – if applicable (attach report)			

<b>Right heart cardiac catheterisation (if performed)</b>		Date of test:	
Testing centre:			
Pulmonary capillary wedge pressure:		Threshold: $\leq 15$ mmHg	
Pulmonary artery pressures:	Mean:		Threshold $> 25$ mmHg at rest
	Systolic:		Diastolic:
Mean right atrial pressure:			
Pulmonary vascular resistance – Wood units:		<input type="checkbox"/> Pulmonary vascular resistance Indexed	
Cardiac output:			
Cardiac index:			
<b>Cardiac catheter contraindicated:</b>			
Discussion:			
<b>Echocardiography (please attach report)</b>		Date of test:	
Estimate of PA pressure			
How obtained? (TR jet vs PDA or other)			
Systemic BP			
RV dilation			
RV function			
Structural congenital heart disease (please describe)			

**Renewal Application for Funding of Pulmonary Arterial Hypertension Treatment . Application for children less than 10 years for PDE-5 inhibitor (sildenafil) treatment**

This form is applicable for younger patients requiring PDE-5 inhibitor (**sildenafil**) monotherapy only. If other treatments are required use the form for adults and children aged over 10 years.

**Date of Application:** \_\_\_\_\_

**Please send applications to:**

PAH Panel Coordinator  
PHARMAC  
P O Box 10-254  
WELLINGTON

Phone: 04 9167 512

Facsimile: 04 974 4858

Email: [PAH@pharmac.govt.nz](mailto:PAH@pharmac.govt.nz)

*Applications **must** be **complete** and accompanied by supporting data where required.*

**Have you attached:**

- Echocardiography report
- Cardiac catheterisation report
- CT report

Patient Details – patient sticker is acceptable			
Surname:			
First name/s:			
NHI No:			
Gender:	<input type="checkbox"/> Male <input type="checkbox"/> Female		
D.O.B:			
Address:			
Phone No:	Home:	Work:	Mobile:
Email:			

Physician Details	
Name:	
NZMC Registration Number:	
Practice Address:	
Phone No:	
Mobile No:	
Fax No:	
Email:	

Signature of applying physician:

**Treatment requested**

- Phosphodiesterase type-5 inhibitors [*sildenafil*]
  
- Suspension required.** Please indicate which suspension product will be used:
  - Methycellulose or water. Available via community funding, dispensed by HP1 community pharmacies and hospital pharmacies.
  - Ora-Blend or Ora-Plus or Ora-Sweet. Available via DHB Hospital funding, dispensed only by hospital pharmacies. Please ensure that the funding DHB hospital has agreed to pay for this suspending product.

Please discuss patient’s progress on treatment and evidence for response:

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In addition to anticipated duration, please describe proposed criteria for weaning therapy. Note - If ongoing therapy planned at 1 year of age (or following a year of therapy) it is recommended consideration should be given to risk/benefit of cardiac catheterisation if not performed prior.

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<b>Basis of request for PAH treatments</b>	
<b>Diagnosis</b>	<b>Tick</b>
Patient has been diagnosed as having pulmonary arterial hypertension	<input type="checkbox"/>
<b>WHO (Venice) clinical classification</b>	
<u>Group One</u> – Pulmonary arterial hypertension	
Idiopathic PAH	<input type="checkbox"/>
Familial PAH	<input type="checkbox"/>
Associated with other diseases:	
Connective tissue disease	<input type="checkbox"/>
Congenital systemic pulmonary shunts	<input type="checkbox"/>
Portal hypertension	<input type="checkbox"/>
HIV infection	<input type="checkbox"/>
Drugs/toxins	<input type="checkbox"/>
Other (specify):	<input type="checkbox"/>
Associated with significant venous or capillary involvement	
Pulmonary veno-occlusive disease	<input type="checkbox"/>
Pulmonary capillary haemangiomas	<input type="checkbox"/>
Persistent pulmonary hypertension of the newborn	<input type="checkbox"/>
<u>Group Four</u> – Pulmonary hypertension due to chronic thrombotic and/or embolic disease only	<input type="checkbox"/>
<u>Group Five</u> – Other pulmonary hypertension (specify)	<input type="checkbox"/>

Test results				
Height (cm):		Weight (kg):		
Height centile:		Weight centile:		
Oxygen Saturations	On Room air _____		On Oxygen at ___ Litres/min: _____	
Current oxygen use:				
Results of overnight oximetry:				
Hospital admissions since approval (please list dates and diagnoses)				
ICU days since approval:				
Chest X Ray findings:				
<b>Six minute walk test: (if relevant)</b>			Date of test:	
Distance walked (m):				
SpO2:	Baseline:		Nadir:	
Heart Rate:	Baseline:		Maximum:	
Borg Index:	Pre:		Post:	
<b>Other:</b>				
Brain natriuretic peptide if available – please provide reference data:				
Radiology CT Chest results – if applicable (attach report)				

<b>Right Heart Cardiac Catheter (please attach reports)</b>		
Date of test: Testing centre:		
	Date of current catheter:	Date of previous catheter:
Pulmonary capillary wedge pressure: (Threshold: $\leq 15$ mmHg)		
Pulmonary artery pressures: (mPAP $>25$ mmHg at rest)	Mean:	
	Systolic:	
	Diastolic:	
Mean right atrial pressure:		
Pulmonary vascular resistance:	<input type="checkbox"/> Wood units	
Cardiac output		
Cardiac index		
<b>Cardiac catheter contraindicated:</b>		
Discussion:		
<b>Echocardiography (please attach report)</b>		
	Date of current echo:	Date of previous echo:
Estimate of PA pressure:		
How obtained? (TR jet vs PDA or other)		
Systemic BP:		
RV dilation:		
RV function:		
Structural congenital heart disease (please describe):		