NHS
England

CPAG Summary Report for Clinical Panel - Balloon pulmonary angioplasty for patient with inoperable chronic thromboembolic pulmonary hypertension

The Benefits of the Proposition			
No	*Metric*	*Grade of evidence*	*Summary from evidence review*
1.	Survival	Grade B	The best available estimate of survival was based on 68 patients, of whom 66 (97%) were alive at one year following Balloon Pulmonary Angioplasty (BPA) (Mizoguchi 2012). Direct comparisons to survival of patients treated with riociguat or other medical therapies were not available. In a different study, one-year survival among 275 patients with chronic thrombo embolic pulmonary hypertension who were not operated upon was 88%. (Delcroix 2016b).

There are two key limitations in this evidence. Firstly there has been no direct comparison of survival in a randomised trial, so the lower survival in the Delcroix study might be because that group of patients had more severe illness than the patients who were given the operation in Mizoguchi's study.

Secondly, there is no evidence on long term survival (for example at three or five years) in the BPA group compared to equivalent patients treated with commissioned drugs such as riociguat. |
| 2. | Progression free survival | Not measured | |
| 3. | Mobility | Grade B | The six minute walk distance (6MWD) measures how far patients can walk in 6 minutes; this distance falls with increasing severity of illness. |

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			The average improvement in the 6MWD ranged from 46 to 100 metres across the studies Additionally, consistent improvements in functional classification and exercise testing were also reported.
4.	Self-care	Not measured	
5.	Usual activities	Not measured	
6.	Pain	Not measured	
7.	Anxiety / Depression	Not measured	
8.	Replacement of more toxic treatment	Not measured	
9.	Dependency on care giver / supporting independence	Not measured	
10.	Safety	Grade B	In the 6 studies which reported complications, 5/281 (2%) of patients died as a result of the procedure. The main complications reported were: injury to the pulmonary artery with the guidewire during balloon pulmonary angioplasty (BPA), which may cause serious bleeding or death; and reperfusion pulmonary oedema (reperfusion pulmonary oedema is were tissue damage occurs following blood supply returning to the tissue following a period of lack of oxygen. The tissue damage affects numerous air sacs in the lungs, making it difficult to breathe, which may necessitate artificial ventilation).
11.	Delivery of intervention	Not measured	

Other health metrics determined by the evidence review

No	Metric	Grade of evidence	Summary from evidence review
12	Measures of function and physiology:	Grade B	In the research literature, there are in addition to 6MWD discussed above, three main measures of how well the heart is working: the New York Heart Association Classification, 6MWD, Pulmonary Vascular Resistance and Brain Naturietic Peptide (BNP). These measures are all used in standard clinical practice in the NHS. They are considered separately in section 13 – 15 below.
13	The New York Heart Association Classification	Grade B	The New York Heart Association classification categorises patients according to whether they suffer symptoms at rest (Class IV), on mild exertion (Class III), on moderate exertion (Class II) or on severe exertion (Class I).
			Five studies reported on changes in functional class after BPA. These are not easily summarised but all studies found an average improvement with fewer patients in classes III and IV.
			This measured benefit implies considerable improvement in quality of life.
			As noted above the main limitation of the studies is lack of long term follow up to provide evidence on outcomes to 3 years and beyond.
14	Pulmonary Vascular Resistance	Grade B	Pulmonary vascular resistance is a measure of how difficult it is for blood to flow through the main arteries of the lung; with pulmonary hypertension, the resistance is increased and flow lessens.
			Reductions in average pulmonary vascular resistance ranged from 31% to 61% across the studies.
			This measured benefit is large and predictive of considerable improvement in quality of life and

			survival.
			As noted above the main limitation of the studies is lack of long term follow up to provide evidence on outcomes to 3 years and beyond.
15	Brain Naturietic Peptide (BNP)	Grade B	BNP is a chemical which is produced in increased quantities when the heart is under stress.
			Reduction in average BNP ranged from 10% to 50%.
			This measured benefit is large and implies considerable improvement in quality of life and survival.
			As noted above the main limitation of the studies is lack of long term follow up to provide evidence on outcomes to 3 years and beyond.