Engagement Report for Clinical Commissioning Policies

Unique Reference Number	A11X04
Policy Title	Selexipag in the treatment of Pulmonary Arterial Hypertension
Accountable Commissioner	Kathy Blacker
Clinical Reference Group	Pulmonary Hypertension
Which stakeholders were contacted to be involved in policy development?	All CRG members and registered stakeholders.
Identify the relevant Royal College or Professional Society to the policy and indicate how they have been involved	Representatives of relevant Royal College or Professional Societies were contacted for Stakeholder Testing as part of the CRG.
Which stakeholders have actually been involved?	All of the key stakeholders listed above were invited to comment.
Explain reason if there is any difference from previous question	Not applicable.
Identify any particular stakeholder organisations that may be key to the policy development that you have approached that have yet to be engaged. Indicate why?	CRG stakeholder identified two additional organisations not already contacted who will be invited to respond to the consultation: the Scottish Medicines Consortium (SMC) and All Waled Medicines Strategy Group (AWMSG).

How have the stakeholders been involved? What engagement methods have been used?	The draft policy proposition and evidence review was circulated to the full membership of the CRG and registered stakeholders for their views, both to establish whether any amendments to the policy are required, and to understand from their perspective what the key questions to ask at consultation might be. Three responses were received – one from a pharmaceutical company, one from a patient organisation and one from a clinician. None supported a non-routine commissioning position. No new peer reviewed, published evidence was identified. The manufacturer noted that a lack of engagement with itself regarding available, though unpublished, clinical evidence resulted in an incomplete evidence review. Furthermore, it queried elements of the content of the evidence review summary. It also felt that the policy had been de-prioritised and less effort put towards its development as a result of a decision by the Policy Working Group to await the publication of a key trial. Both the manufacturer and the clinician noted that the composite primary endpoint used in the main clinical study was not adequately reflected in the evidence review summary. The clinician also felt that the statement within the evidence review regarding potential bias was unduly negative. Both the manufacturer and the patient organisation noted that they wished to be more involved in policy development work. The concerns raised regarding non-routine commissioning of selexipag for pulmonary arterial hypertension were: • Lack of choice for patients • No alternative treatment available for patients who have failed other treatments (equality). • A failure to appreciate the benefits of selexipag as an oral treatment acting on the prostacyclin pathway compared with current treatments which carry higher burdens of treatment for both the patient and the healthcare provider. • A different decision by NHS England, compared with Wales and Scotland. • The points made regarding composite endpoint and potential bias were considered by the evidence reviewer, who considered that the composite endpoint had been fairly reflected within the evidence review summary and that the point regarding potential bias of an industry funded trial was reasonable. The manufacturer supported a 30-day consultation period. The remaining two stakeholders gave no response.
What has happened or changed as a result of their input?	The PWG has considered the feedback received and its responses are as follows: • The points made regarding unpublished evidence and alignment with Scotland and Wales were discounted as these are outside the remit of the policy development process. • The points made regarding consistency of application of process for this policy were discounted, as these are not relevant to the development of this policy proposition. • The points made regarding involvement of the wider clinical body were considered and have been addressed through stakeholder testing and plans for consultation. One minor update was made to the policy proposition.

How are stakeholders been informed of progress with policy development as a result of their input?	This engagement report, along with the updated policy proposition will be circulated as part of the public consultation. Stakeholders will be notified and invited to comment further.
What level of wider public consultation is recommended by the CRG for the NPOC Board to agree as a result of stakeholder involvement?	Public consultation for 30 days, as supported by the majority of stakeholders.