Consultation Report

Topic details

Title of policy:	Selexipag for treating pulmonary arterial hypertension (PAH)
Programme of Care:	Internal Medicine
Clinical Reference Group:	Specialised Respiratory
URN:	170104P

1. Summary

This report summarises the outcome of the public consultation that was undertaken to test the policy proposal.

2. Background

Pulmonary arterial hypertension (PAH) is a severe, progressive and usually fatal disease with a prognosis worse than many forms of common cancer. It is caused by changes in the smaller branches of the pulmonary arteries (the arteries that carry blood from the heart to the lungs). The main treatment for people with PAH is medicines directed at the pulmonary vasculature (blood vessels connecting the heart and the lungs). This policy proposition about selexipag treatment for PAH concludes that there is sufficient evidence to support a proposal for routine commissioning and the National Programme of Care (NPoC) Board supports that it should be routinely commissioned**.**

3. Publication of consultation

The policy proposition was published and sign-posted on NHS England's website and was open to consultation feedback for a period of 30 days from 2nd March 2018 to 1st April 2018. Consultation comments were shared with the Policy Working Group to enable full consideration of feedback and to support a decision on whether any changes to the policy might be recommended.

Respondents were asked the following consultation questions:

- Has all the relevant evidence been taken into account?
- Does the impact assessment fairly reflect the likely activity, budget and service impact? If not, what is inaccurate?
- Does the policy proposition accurately describe the current patient pathway that patients experience? If not, what is different?
- Please provide any comments that you may have about the potential impact on equality and health inequalities which might arise as a result of the proposed changes that have been described?

- Are there any changes or additions you think need to made to this document, and why?

4. Results of consultation

There were two responses to the consultation - one from Actelion, the manufacturer of the product and one from the manufacturer of another product used to treat patients at a similar stage in the pathway.

Actelion noted that selexipag is in tablet form so provides an oral alternative that is easier to take than the currently commissioned prostanoids and that in their view most patients do not receive prostanoids as part of the PAH treatment pathway.

The responses from another manufacturer – MSD - were considered. These covered 4 main points; the evidence base in their view over stated the benefits of selexipag, the methodology on the number of patients likely to be eligible was considered high, the calculation of VAT was unclear and the rationale for the role of selexipag was inconsistent with the actual policy proposal.

In regards to the points raised by MSD, NHS England noted the methodology used in the NICE Commissioning Support Programme process does have some differences to the process compared to previous years but the NPoC and NICE with the Policy Working Group (PWG) reviewed this information as part of the assurance process and did not consider further changes should be made to the evidence review, nor the calculation of VAT.

The PWG reviewed the proposed number of patients eligible for treatment with selexipag and revised this to reflect that a higher percentage may cease treatment due to the side effects and amended the wording to make it clearer that selexipag is primarily proposed as an additional treatment and not, except for a small number of patients, as an alternative to commissioned prostaglandins but otherwise confirmed the pathway described was as intended by the PWG.

5. How have consultation responses been considered?

Responses have been carefully considered and noted in line with the following categories:

- Level 1: Incorporated into draft document immediately to improve accuracy or clarity
- Level 2: Issue has already been considered by the CRG in its development and therefore draft document requires no further change
- Level 3: Could result in a more substantial change, requiring further consideration by the CRG in its work programme and as part of the next iteration of the document
- Level 4: Falls outside of the scope of the specification and NHS England's direct commissioning responsibility

6. Has anything been changed in the policy as a result of the consultation?

The policy proposal was amended to confirm the proposal would enable prescribing of prostanoids primarily to patients not yet receiving this class of treatment intravenously (IV) so in most cases this treatment would replace other oral treatments – not other prostanoids. In a very small minority of cases patients with disabilities who are currently unable to have IV prostanoid might receive an oral prostanoid instead.

The PWG reviewed the proposed number of patients eligible for treatment with selexipag and revised this to reflect that a higher percentage may start but then cease treatment due to the side effects.

7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposal?

No