

Engagement Report for Specialised Commissioning Policies

Unique Reference Number and NICE ID	1679 ID003
Policy Title	Lomitapide for treating homozygous familial hypercholesterolaemia
Accountable Commissioner	Sarah Watson
Clinical Lead	Handrean Soran
Clinical Reference Group	Specialised Endocrinology
Which stakeholders were contacted to be involved in policy development?	Specialised Endocrinology CRG and registered stakeholders Cardiothoracic CRG and registered stakeholders British Cardiac Patients Association British Heart Foundation Blood Pressure UK Cardiovascular Care Partnership CLIMB Coronary Prevention Group Genetic Alliance UK HEART UK Rare Disease UK South Yorkshire Cardiothoracic Centre Specialised Healthcare Alliance
Identify the relevant Royal College or Professional Society to the policy and indicate how they have been involved	
Which stakeholders have actually been involved?	Internal Medicine CRG and registered stakeholders HEART UK
Explain reason if there is any difference from previous	Organisations declined the offer to participate in the development of the policy

question	
<p>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?</p>	<p>None, the main patient and carer representative organisation (HEART UK) was involved throughout the development of the draft policy proposition.</p> <p>It has also been confirmed that further comment would be welcomed during the period of public consultation.</p>
<p>How have stakeholders been involved? What engagement methods have been used?</p>	<p>Policy working group meeting and subsequent contact for policy development.</p> <p>Stakeholder engagement process. 14 day email engagement exercise with registered stakeholders</p>
<p>What has happened or changed as a result of their input?</p>	<p>Comments have been reviewed by policy working group and amendments made to documents where appropriate following consideration by the Policy Working Group. Eight submissions were made in the 14 day stakeholder consultation. Several responses were supportive and didn't have suggestions for change. Issues raised focussed primarily on the treatment pathway, including:</p> <ul style="list-style-type: none"> i. It was requested that the apheresis centres were named in the policy. However the PWG decided not to make this change because NHS England does not commission these apheresis services. Centres will be contacted during public consultation, any issues raised will need to be picked up in the commissioning plan, and, if the policy is agreed, advice given to commissioning hubs. ii. It was requested that the policy be amended to state that patients may be able to stop or reduce the frequency of adjunctive medicines when starting lomitapide. The PWG did not feel the evidence supported this. It also felt that, in clinical practice, if patients were able to reduce the frequency of medicines, they would reduce lomitapide rather than the established cholesterol lowering treatments which have more of a known adverse event profile. Furthermore, the PWG noted that the policy already states that patients may be able to consider reducing the frequency of lipoprotein apheresis (mechanical removal of cholesterol from the blood) after initiating treatment with lomitapide. iii. The policy recommends lomitapide only if it has not been controlled on existing treatments (and these treatments are listed). A stakeholder requested that the existing criteria for commissioning be updated to clarify that people do not need to have all these treatments to be eligible for lomitapide e.g. a patient may have a contraindication to these treatments. However the PWG noted that the policy already accounts for this by stating "as long as they are clinically indicated", so it

	<p>agreed no further clarification was needed.</p> <p>iv. Further clarification was requested about the place of liver transplantation in the pathway. However the PWG agreed no change was needed because the policy already states at several points that it is only performed if disease progresses despite all other treatments, and that it is performed very rarely for people with HoFH.</p> <p>v. A clarification was made to the discontinuation criteria.</p>
<p>How are stakeholders being kept informed of progress with policy development as a result of their input?</p>	<p>Stakeholders will be kept informed of the policy's progress through NHS England's consultation portal website</p>
<p>What level of wider public consultation is recommended by the CRG for the NPOC Board to agree as a result of stakeholder involvement?</p>	<p>Not all stakeholders made a recommendation. Those that did selected:</p> <p>1 - changes that could reasonably be expected to be broadly supported by stakeholders - up to 6 week consultation</p>

Draft for public consultation