NICE National Institute for Health and Care Excellence

NHS England

Engagement Report for Specialised Commissioning Policies

Unique Reference Number and NICE ID	1810 ID011
Policy Title	Idebenone for treating Leber's hereditary optic neuropathy (in patients over 12 years of age)
Clinical Reference Group	Specialised Ear and Ophthalmology Clinical Reference Group
Which stakeholders were contacted to be involved in policy development?	A policy working group was established in line with NHS England's standard methods. The draft policy proposition was sent to the following groups for comment: • Specialised Ear and Ophthalmology Clinical Reference Group registered stakeholders
Identify the relevant Royal College or Professional Society to the policy and indicate how they have been involved	All of the relevant Royal Colleges and professional societies were invited to take part in stakeholder testing.
Which stakeholders have actually been involved?	7 responses were received from stakeholders, including 1 individual clinician. Santhera LHON Society Fight for Sight The Lily Foundation Royal College of Ophthalmologists Royal National Institute of Blind People (RNIB)
Explain reason if there is any difference from previous question	Not all organisations commented on the documents.
Identify any particular stakeholder organisations that may	None, the main patient and carer representative organisations were involved throughout the development of the draft policy proposition.

be key to the policy development that you have approached that have yet to be engaged. Indicate why?	
How have stakeholders been involved? What engagement methods have been used?	Policy working group meeting and subsequent contact for policy development. The draft policy proposition was distributed to stakeholders via email for a period of two weeks of stakeholder testing, in preparation for public consultation. Stakeholders were asked to submit their responses via email, using a standard response and in line with NHS England's standard processes for developing clinical commissioning policies.
What has happened or changed as a result of their input?	Comments were submitted by 7 stakeholders and these have been reviewed by the policy working group. Comments included: • A statement that using the pivotal trial as the main evidence base for the policy was not appropriate, because the trial was flawed. No change will be made because this was the main study for the drug (the European public assessment report notes that the RHODOS trial was considered the "main support for efficacy" for idebenone in this indication), plus data from all appropriate sources was fully explored. • A suggestion that the decision was based on economic reasons not clinical. No change will be made as at this stage decision making is based on clinical evidence only. • A request for a minor amendment to text as follows, which we have agreed: Statistical significance was also reached in patients with a disease duration ≥1 year, but there was no significance between-treatment difference for disease duration <1 year.
How are stakeholders being kept informed of progress with policy development as a result of their input?	All stakeholders (including CRG members and registered stakeholders) will be notified when the draft policy proposition goes out to public consultation and will be kept informed of the policy's progress through NHS England's consultation portal website.
What level of wider public consultation is recommended by the	It is proposed that specialised products will be subject to a period of public consultation for four weeks.

CRG for the NPOC Board to agree as a result of stakeholder involvement?	