Engagement Report for Clinical Commissioning Policies

Unique Reference Number	E09X04
Policy Title	Everolimus for subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex
Accountable Commissioner	Penelope Gray
Clinical Reference Group	Paediatric neurosciences
Which stakeholders were contacted to be involved in policy development?	All registered CRG stakeholders, Paediatric Cancer Services CRG, National Network of Parent Carer Forums (NNPCF), British Academy of childhood disability, British Paediatric Neurology Association, Cauldwell Children's Society, British Paediatric Neurosurgery Group, Contact a family, Mencap, MIND UK, Young Minds, Rethink, Neurological Alliance, Royal College of Psychiatrists, Cerebra, Council for Disabled Children, Challenging behaviour foundation, Together for short lives, Child Brain Injury Trust, Royal College of Physicians, Royal College of Paediatricians, Society of British Neurological Surgeons, Tuberous Sclerosis Association, British Neuro-oncology society, Muscular Dystrophy UK and various specialists, including Clinical Geneticists, Adult and Paediatric Neurologists, Neuroradiologist, Neurosurgeons, Adult and Paediatric Nephrologists, Adult and Paediatric Urologists, Interventional radiologists, Dermatologists, Adult and Paediatric Cardiologists, Chest Physicians and CNS Oncologists.
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?	None

How have the stakeholders been involved? What engagement methods have been used?	The draft policy proposition and evidence review were 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. Two responses were received – one from a pharmaceutical company and one from a CRG member. <u>The responses were as follows:</u> (1) The manufacturer identified additional evidence from a recently published phase I/II trial. (2) The manufacturer also requested that the EMA license for all licensed indications be stated for everolimus (Votubia®) in the policy proposal. (3) Moreover, the manufacturer wanted the policy to reflect updated manufacturer guidelines (SPC - Summary of Product Characteristics) on dosing for patients aged 1-3. (4) Furthermore, the manufacturer suggested a change to the Proposed Governance Arrangements proposing that consultation with specialists should replace a mandatory MDT meeting. (5) Lastly, the manufacturer noted that Votubia® had been granted an extension on its exclusivity to 2021, noting it is presently unclear whether it will be able to maintain exclusivity until that time in view of the earlier commercialisation of generics of Afinitor® in the UK (after the original patent expiry date of 2018). (6) Both the manufacturer and the CRG member believed the composition of the MDT should, in the case of neurology, be age-specific.
What has happened or changed as a result of their input?	The PWG has considered the feedback received and has responded: - In response to (1), the PWG noted that the additional evidence would not materially change the proposed commissioning position. - In response to (2) the PWG agreed, however, it noted that only SEGA-related licensing was relevant. Policy updated accordingly. - In response to (3) the PWG agreed. Policy updated accordingly. - In response to (4) the PWG disagreed on the grounds that this is a high-cost specialist drug which needs to be appropriately prescribed and its use controlled. - In response to (5) the PWG noted the fact. Financial impact assessment updated accordingly. - In response to (6) the PWG agreed. Policy updated to reflect requirements for age-speficic neurology specialists.
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 a period of 30 days as supported by stakeholders.