Engagement Report for Clinical Commissioning Policy Statements

Unique Reference Number	1818
Policy Title	Rituximab for the treatment of refractory Focal Segmental Glomerulosclerosis in the native kidney in adults (1818)
Accountable Commissioner	[redacted]
Clinical Reference Group	Renal Services CRG
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: • Renal Services Clinical Reference Group registered stakeholders
Identify the relevant Royal College or Professional Society to the policy and indicate how they have been involved	The relevant Royal Colleges and professional societies were invited to take part in stakeholder testing. • The Royal College of Physicians • The Renal Association
Which stakeholders have actually been involved?	Six responses were received from stakeholders: • Two individuals, • The Royal College of Physicians • The Renal Association • The Renal Pharmacy Group • Kidney Care UK
Explain reason if there is any difference from previous question	Not all organisations commented on the documents.

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, the main patient and carer representative organisations were involved throughout the development of the draft policy proposition and included in stakeholder testing.
How have stakeholders been involved? What engagement methods have been used?	The Policy Working Group 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. 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 six stakeholders and these have been reviewed by the policy working group. Five of the six did not support the policy proposition. These were primarily due to respondents' assessment of evidence which they cited. The additional evidence cited by respondents fell into 3 broad categories: 1. Research studies in children 2. Case reports and case series in post-transplant patients 3. Case reports and case series including patients with a number of underlying conditions not limited to FSGS The Public Health member reviewed the cited evidence and completed an additional evidence report and after further discussion with the PWG concluded these did not add materially to the evidence base for the use of rituximab for FSGS. The PWG and PHE reached this conclusion because the evidence was either: • for a group not covered by the policy statement, • did not demonstrate evidence of material effect • was for a single patient or small cohort or • was vulnerable to bias.

	It was noted that some respondents referred to patients who had a transplanted kidney. It was not the intention of the policy to consider this cohort so the policy title was amended to reference that it covers FSGS in an adult patient's own kidney (native), not in a transplanted organ. The PWG is aware NHS England commissions rituximab for various forms of nephrotic syndrome in children. However, presentation of nephrotic syndrome in children is multifactorial and likely to have a genetic component and FSGS is one cause so comparisons with treatment of adults with FSGS is not straightforward.
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 kept informed of the policy's progress.
What level of wider public consultation is recommended by the CRG for the NPOC Board to agree as a result of stakeholder involvement?	The NPOC Board noted some stakeholders requested Public Consultation of 30 days. The NPOC Board considered the advice that the evidence base is very limited and Public Consultation would not change this position. Also in line with the methods for policy statements only stakeholder engagement is undertaken. This will be confirmed to the PWG and stakeholders.