NICE National Institute for Health and Care Excellence

NHS England

Engagement Report for Specialised Commissioning Policies

Unique Reference Number and NICE ID	1819 ID014
Policy Title	Emicizumab for bleed prevention in severe and moderate haemophilia A without inhibitors
Accountable Commissioner	Will Horsley
Clinical Lead	Pratima Chowdary
Clinical Reference Group	Specialised Blood Disorders
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 Blood Disorders Clinical Reference Group (CRG); and • Registered stakeholders for the Specialised Blood Disorders CRG.
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?	Specialised Blood Disorders CRG and registered stakeholders: 5 responses were received from stakeholders. This included 3 pharmaceutical companies including the manufacturer of Emicizumab, 1 individual clinician and 1 other individual of unknown interest.
Explain reason if there is any difference from	Not all organisations commented on the documents.

previous question	
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
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 5 stakeholders and these have been reviewed by the policy working group. Amendments were made to the documents where appropriate following consideration by the PWG. The amendments included: In the draft policy proposition: • the DPP was updated to reflect the marketing authorisation extension that was granted by the CHMP to emicizumab in the severe HA population without current inhibitors. • The epidemiological data was updated to reflect the anticipated marketing authorisation extension • It was made clear that fewer doses of prophylactic FVIII treatment would need to be carried with patients when travelling • A previously unpublished article reference was updated now that the article has published in a peer-reviewed journal. • The proposed criteria for commissioning were updated to reflect the marketing authorisation • In the "During treatment" section, additional monitoring requirements for the development of inhibitors has been included and a requirement that all surgery and major bleeds in non-inhibitor patients treated with emicizumab prophylaxis should be managed in a Haemophilia CCC which has access to 24-hour bovine chromogenic FVIII testing was added as well • The term "unexplained bleeds" has been superseded by "spontaneous bleeds or bleeds related to activities of daily

	living" a phrase which may be better recognised by the clinical and patient communities. • The treatment pathway diagram was updated • NICE copyright updated to 2019.
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 CRG for the NPOC Board to agree as a result of stakeholder involvement?	Not all stakeholders made a recommendation. 2 stakeholders recommended the following: 1 - changes that could reasonably be expected to be broadly supported by stakeholders - up to 6 week consultation 2 stakeholders recommended: 2 - up to 12 weeks consultation to include some additional proactive engagement activities during the live consultation period