Engagement Report

Topic details

Title of policy or policy statement:	Icatibant for treatment of moderate to severe acute swellings due to bradykinin-mediated angioedema with normal C1 inhibitor (adults) [2315]
Programme of Care:	Blood and infection
Clinical Reference Group:	Immunology and allergy
URN:	2315

1. Summary

This report summarises the feedback NHS England received from engagement during the development of this policy proposition, and how this feedback has been considered.

2. Background

Patients with angioedema have uncontrolled and spontaneous swellings, which can occur episodically and result in a build-up of fluid in various parts of the body. These swellings vary by types and locations, including swellings in the:

- Airway - this is particularly dangerous and can lead to death if the patient is not able to breathe properly.
- Gut - this can cause severe pain in the stomach area, feeling sick (nausea) and being sick (vomiting).
- Deep tissues of the skin - this can cause significant disability for example if the hands, feet or genitals are affected.

Swellings can be spontaneous or occur during times of physiological and psychological stress. They develop as a result of deficiency or improper functioning of certain proteins that help to maintain the normal movement of fluids in and out of blood vessels.

Angioedema can be grouped into different types based on which inflammatory chemicals are triggering them in the body. The two known chemicals involved are histamine and bradykinin. When bradykinin is involved, the condition is referred to as bradykinin-mediated and when histamine is involved, the condition is referred to as histamine-mediated. Bradykinin-mediated angioedema with normal C1 inhibitor is extremely rare, and diagnosing these conditions can be challenging. Diagnosis may involve showing a lack of response to high-dose antihistamines, functional/laboratory studies of bradykinin mediators or, in patients with hereditary angioedema with normal C1-inhibitor (HAE-nC1-INH), a family history or genetic mutations that are associated with bradykinin mediated angioedema with normal C1 inhibitor level.

This policy proposition applies to patients with recurrent, or long-term, symptoms in two subgroups of bradykinin-mediated angioedema with normal C1 inhibitor:

- HAE-nC1-INH
- Idiopathic non-histaminergic angioedema with normal C1-inhibitor (INHA)

This policy proposition does not cover C-1 inhibitor abnormalities or drug induced angioedema.

Current treatment during acute swellings involves observation and if the airway is involved then intensive care admission may be required for intubation (insertion of a tube into the airway). Intubation prevents complete obstruction of the airway, which otherwise would mean the patient is unable to take in oxygen.

The proposed intervention is icatibant, a bradykinin-2 receptor antagonist. After sufficient training, patients can give the treatment themselves, or carers/parents can give the treatment. The treatment can therefore be delivered at home, for patients to self-administer when they start to feel symptoms of swelling developing. Icatibant is currently licensed for symptomatic treatment of acute attacks of hereditary angioedema with C1 deficiency (types 1 and 2) in adults, adolescents and children aged two years and older.

Engagement

The Programme of Care (PoC) has agreed that the proposition offers a clear and positive impact on patient treatment, by potentially making a new treatment available which widens the range of treatment options without disrupting current care or limiting patient choice, and therefore further public consultation was not required. This has been assured by the Patient Public Voice Advisory Group.

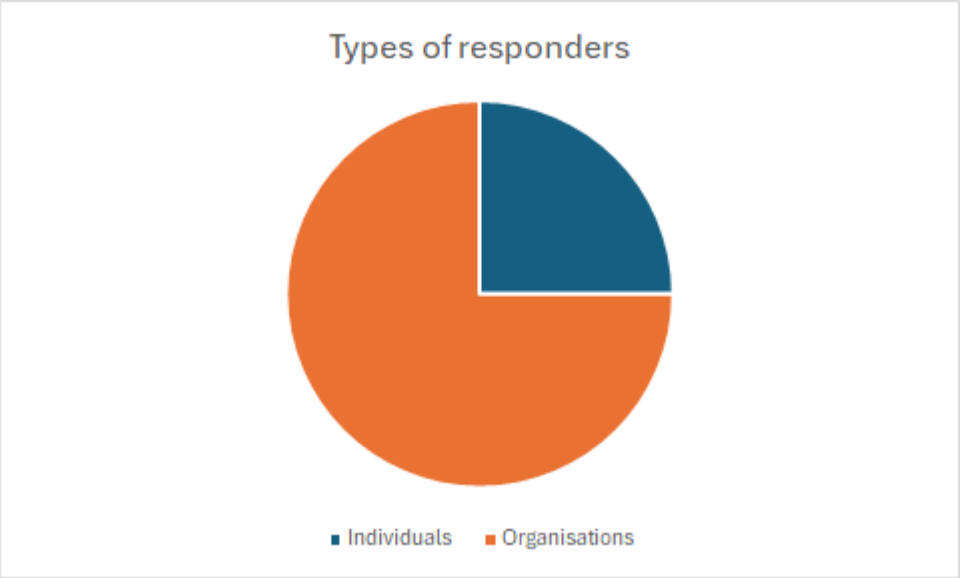
The policy proposition underwent a three-week stakeholder testing between the 16th of August and 13th September 2024 with registered stakeholders from the following Clinical Reference Groups:

- Specialised Immunology and Allergy Services

Respondents were asked the following consultation questions:

- Do you believe that there is any additional information that we should have considered in the evidence review?
- Do you agree with the policy inclusion criteria?
- Do you agree with the policy exclusion criteria?
- Do you believe that there are any potential positive and/or negative impacts on patient care as a result of making this treatment option available?
- Do you support the Equality and Health Inequalities Impact Assessment (EHIA)?
- Does the Patient Impact Assessment (PIA) present a true reflection of the patient and carers lived experience of this condition?
- Do you have any further comments on the policy proposal?
- Do you have any potential conflict of interest relating to this document or service area?

3. Engagement Results



There were 8 responses from stakeholders:

- 6 on behalf of organisations
- 2 individuals

In line with the 13Q assessment it was deemed that further public consultation was not required.

4. How has feedback been considered?

Responses to engagement have been reviewed by the Policy Working Group (PWG) and the Blood and Infection PoC. The following themes were raised during engagement:

Key themes in feedback	NHS England Response
Relevant Evidence	
One responder stated that the inclusion criteria should include ACEi (a drug-induced angioedema) but no additional evidence was provided. All other stakeholders did not believe any additional evidence should have been considered in the evidence review.	Noted. In patients with the disease subtype of drug-induced bradykinin-mediated angioedema with normal C1 inhibitor, evidence of varying certainty was returned in trials using icatibant, some of which were placebo controlled randomised trials that showed no significant differences in outcomes between the two groups. Given the significant limitations in terms of interpreting these findings, there was insufficient evidence returned in the evidence review for the PWG to include this group.
Impact Assessment	
All stakeholders felt this policy would have a positive impact on patient care	No action required.
All stakeholders that responded felt the patient impact assessment presented a true	No action required.

reflection of the patient and carers lived experience of the condition.	
Inclusion criteria	
One responder raised that dermatologists or allergists might also treat patients with angioedema without wheals but currently the inclusion criteria is a diagnosis made by an immunologist.	The policy proposition was changed to 'diagnosis should be made by an immunologist or **an allergist**'. In the PWG experience, not many dermatologists see patients with angioedema in the NHS so therefore the proposition was not expanded to include dermatology services.
Potential impact on equality and health inequalities	
All stakeholders supported the Equality and Health Inequalities Impact Assessment	No action required.
Changes/addition to policy	
'Diagnosis should be made by an immunologist or **an allergist**'	N/A

5. Has anything been changed in the policy proposition as a result of the stakeholder testing and consultation?

The following change(s) based on the engagement responses has (have) been made to the policy proposition:

- Wording changed in inclusion criteria that 'Diagnosis should be made by an immunologist **or an allergist'**

6. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?

No