

NHS England: Equality and Health Inequalities Impact Assessment (EHIA)

A completed copy of this form must be provided to the decision-makers in relation to your proposal. The decision-makers must consider the results of this assessment when they make their decision about your proposal.

1. **Name of the proposal (policy, proposition, programme, proposal or initiative): 2315 Icatibant for treatment of moderate to severe acute swellings due to bradykinin-mediated angioedema with normal C1 inhibitor (adults)**
2. **Brief summary of the proposal in a few sentences**

This is a clinical commissioning policy which proposes the use of Icatibant for the treatment of moderate to severe acute swellings due to bradykinin-mediated angioedema with normal C1 inhibitor.

Angioedema is a condition characterised by excessive fluid extravasation in deep dermal, subdermal and mucosal tissue spontaneously or during times of physiological and psychological stress which causes localised swellings, sometimes known as attacks. Bradykinin-mediated angioedema is difficult to treat because it does not respond to common and effective treatments such as steroids or antihistamines. The most common bradykinin-mediated angioedema is hereditary angioedema types I and II which is caused by a deficiency/dysfunction of a protein called C1-esterase inhibitor (C1 inhibitor). The population in this proposed policy is patients with a distinct form of bradykinin-mediated angioedema that is not associated with C1 inhibitor abnormalities. Registry data shows that patients with hereditary angioedema with normal C1 inhibitor are more likely to experience laryngeal swellings than those with C1 inhibitor deficiency, and laryngeal involvement in this condition is potentially fatal.

Icatibant is currently licensed for symptomatic treatment of acute attacks of hereditary angioedema with C1 inhibitor deficiency (HAE 1 and 2) in adults, adolescents and children aged 2 years and older. This policy proposes an off-label use for adult patients with bradykinin-mediated angioedema but a normal C1 inhibitor function.

3. **Main potential positive or adverse impact of the proposal for protected characteristic groups summarised**
Please briefly summarise the main potential impact (positive or negative) on people with the nine protected characteristics (as listed below). Please state **N/A if your proposal will not impact adversely or positively on the protected characteristic groups listed below. Please note that these groups may also experience health inequalities.**

| Protected characteristic groups | Summary explanation of the main potential positive or adverse impact of your proposal | Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact |
|---|---|--|
| <p>Age: older people; middle years; early years; children and young people.</p> | <p>The mean age of first attack is 27 years but patients as young as 12 years have been described in the literature. Swellings can last for several days and result in an inability to work or attend school.</p> <p>There are no licensed treatment options for prophylaxis or for acute swellings. Some of the unlicensed prophylactic treatments are contraindicated in patients under 18 years.</p> | <p>This policy is restricted to adults in line with the findings from the evidence review. However, as icatibant has a licensed indication in children aged two years and older for other conditions, NHS England's Policy 170001/P Commissioning Medicines for Children in Specialised Services (commissioning medicines children) can be applied to this policy for children with bradykinin-mediated angioedema with normal C1 inhibitor aged two years and older if clinically eligible.</p> |
| <p>Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.</p> | <p>This group of patients can develop swellings in any part of their bodies including life-threatening swellings of tongue, larynx and pharynx. When swellings involve the feet, this will interfere with mobility as not only would shoes be impossible to wear, but walking is virtually impossible.</p> <p>Recurrent hospital admissions can significantly interfere with patient ability to self-care, due to inability to walk/ get to the toilet associated with feet swellings; inability to hold a knife and fork and therefore self feed or use the toilet if swellings affect upper limb; temporary</p> | <p>Provision of icatibant would prevent acute episodes of this disorder and associated impairment.</p> |

| Protected characteristic groups | Summary explanation of the main potential positive or adverse impact of your proposal | Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact |
|--|---|---|
| | <p>eyelid closure and therefore 'blindness' when swellings affect eyes.</p> <p>Icatibant has been shown to be effective in resolution of acute episodes, improving physical and mental health and reducing the impact of a long-term condition. The policy includes self-administration, which may be useful in terms of accessing treatment for those with access needs due to disability.</p> | |
| Gender Reassignment and/or people who identify as Transgender | There is no identified impact of this policy on this protected characteristic. | N/A |
| Marriage & Civil Partnership: people married or in a civil partnership. | There is no identified impact of this policy on this protected characteristic. | N/A |
| Pregnancy and Maternity: women before and after childbirth and who are breastfeeding. | The licence for icatibant states that it should only be used in pregnancy if the benefit justifies the risk to the foetus. It also specifies that women should not breastfeed for 12 hours after treatment. | Clinicians should discuss the risks and benefits with each individual patient to help them make an informed decision about the treatment. |
| Race and ethnicity¹ | This policy will promote access to icatibant regardless of ethnicity. Ethnicity | This policy aims to make icatibant available for all patients with severe acute swellings due to |

¹ Addressing racial inequalities is about identifying any ethnic group that experiences inequalities. Race and ethnicity includes people from any ethnic group incl. BME communities, non-English speakers, Gypsies, Roma and Travelers, migrants etc. who experience inequalities so includes addressing the needs of BME communities but is not limited to addressing their needs, it is equally important to

| Protected characteristic groups | Summary explanation of the main potential positive or adverse impact of your proposal | Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact |
|---|--|---|
| | is not known to be a risk factor for bradykinin-mediated angioedema with normal C1 inhibitor. | bradykinin-mediated angioedema with normal C1 inhibitor regardless of ethnicity. |
| Religion and belief: people with different religions/faiths or beliefs, or none. | There is no identified impact of this policy on this protected characteristic. | N/A |
| Sex: men; women | <p>Oestrogen has been identified as a trigger factor for acute swellings and the condition particularly affects women; one French study identified that over 80% of patients with HAE with normal C1 inhibitor were female.</p> <p>This policy is therefore expected to have a positive impact on this characteristic as a new treatment option.</p> | This policy aims to make icatibant available for all patients with severe acute swellings due to bradykinin-mediated angioedema with normal C1 inhibitor regardless of sex. |
| Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual. | There is no identified impact of this policy on this protected characteristic. | N/A |

4. Main potential positive or adverse impact for people who experience health inequalities summarised

Please briefly summarise the main potential impact (positive or negative) on people at particular risk of health inequalities (as listed below). Please state **N/A if your proposal will not impact on patients who experience health inequalities.**

recognise the needs of White groups that experience inequalities. The Equality Act 2010 also prohibits discrimination on the basis of nationality and ethnic or national origins, issues related to national origin and nationality.

| Groups who face health inequalities ² | Summary explanation of the main potential positive or adverse impact of your proposal | Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact |
|--|---|---|
| Looked after children and young people | <p>People from these groups often experience difficulties accessing services and accessing follow up. However, by reducing the severity of symptoms and need for emergency care admissions, this policy is expected to have a positive effect on the overall survival and overall outcomes of looked after children and young people. The proposed use of icatibant via the subcutaneous route with the option for self-administration may be advantageous in this setting.</p> <p>The associated reduction in hospital admissions will also have a positive impact for this group.</p> | <p>This policy is restricted to adults in line with the findings from the evidence review. However, as icatibant has a licenced indication in children aged two years and older for other conditions, NHS England's Policy 170001/P Commissioning Medicines for Children in Specialised Services (commissioning medicines children) can be applied to this policy for children with bradykinin-mediated angioedema with normal C1 inhibitor aged two years and older if clinically eligible.</p> <p>If patient factors mean that self-administration is not possible, options for health-practitioner support can be considered.</p> <p>Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to mitigate the risks for this group.</p> |
| Carers of patients: unpaid, family members. | This policy should have a positive impact for carers as the severity of symptoms and hospital admissions will reduce. The use of subcutaneous icatibant with the option for self-administration as proposed in the policy may be advantageous for carers as it can be administered outside of hospital. | N/A |

² Please note many groups who share protected characteristics have also been identified as facing health inequalities.

| Groups who face health inequalities² | Summary explanation of the main potential positive or adverse impact of your proposal | Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact |
|---|--|--|
| Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs. | People from this group often experience difficulties accessing services and accessing follow up. The proposed use of icanibant via the subcutaneous route with the option for self-administration may be advantageous in this setting. | Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to mitigate the risks for this group |
| People involved in the criminal justice system: offenders in prison/on probation, ex-offenders. | People from this group often experience difficulties accessing services and accessing follow up. The proposed use of icanibant via the subcutaneous route with the option for self-administration may be challenging in this environment, as patients may not be able to keep this equipment nearby, resulting in a potential delay in administration. | Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to mitigate the risks for this group. |
| People with addictions and/or substance misuse issues | There is no identified impact of this policy on this group who face health inequalities. | N/A |
| People or families on a low income | This policy will likely reduce the financial burden on families from frequent trips to hospital. | N/A |
| People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills). | People from this group often experience difficulties accessing services and accessing follow up. Training for self-administration may be difficult. For patients and carers with poor literacy or understanding of the health service. | Provision of training and support regarding self-administration to patients and carers is essential, including verbal and written mediums of training tools, translated and Easy Read materials. |

| Groups who face health inequalities² | Summary explanation of the main potential positive or adverse impact of your proposal | Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact |
|--|--|--|
| People living in deprived areas | There is no identified impact of this policy on this group who face health inequalities. | N/A |
| People living in remote, rural and island locations | This policy should have a positive impact for people living in remote, rural and island locations as it will be reducing the severity of symptoms and is likely to reduce the need for access to emergency care. Furthermore, the use of subcutaneous icatibant with the option for self-administration as proposed in the policy may be advantageous in this setting. | N/A |
| Refugees, asylum seekers or those experiencing modern slavery | People from this group often experience difficulties accessing services and accessing follow up. The proposed use of icatibant via the subcutaneous route with the option for self-administration may be advantageous in this setting. | Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to mitigate the risks for this group. Provision of training and support regarding self-administration to patients and carers is essential, including verbal and written mediums of training tools, translated and Easy Read materials. |
| Other groups experiencing health inequalities (please describe) | There are no further direct negative or positive impacts of this policy on any other groups experiencing health inequalities. | N/A |

5. Engagement and consultation

a. Have any key engagement or consultative activities been undertaken that considered how to address equalities issues or reduce health inequalities? Please place an x in the appropriate box below.

| | | |
|--------------|-----------|--------------------|
| Yes X | No | Do Not Know |
|--------------|-----------|--------------------|

b. If yes, please briefly list up the top 3 most important engagement or consultation activities undertaken, the main findings and when the engagement and consultative activities were undertaken.

| Name of engagement and consultative activities undertaken | | Summary note of the engagement or consultative activity undertaken | Month/Year |
|--|---------------------|---|--------------------|
| 1 | Stakeholder testing | The policy went out for a period of stakeholder testing during August 2024. | August 2024 |
| 2 | | | |
| 3 | | | |

6. What key sources of evidence have informed your impact assessment and are there key gaps in the evidence?

| Evidence Type | Key sources of available evidence | Key gaps in evidence |
|---------------------------|---|--|
| Published evidence | <p>Bouillet, L., Boccon-Gibod, I., Launay, D., Gompel, A., Kanny, G., Fabien, V., Fain, O. and IOS Study Group, 2017. Hereditary angioedema with normal C1 inhibitor in a French cohort: clinical characteristics and response to treatment with icatibant. <i>Immunity, Inflammation and Disease</i>, 5(1), pp.29-36.</p> <p>Jones, D.H., Bansal, P., Bernstein, J.A., Fatteh, S., Harper, J., Hsu, F.I., O'Connor, M., Park, N. and Suez, D., 2022. Clinical profile and treatment outcomes in patients with hereditary</p> | There was no evidence identified for cost effectiveness. |

| Evidence Type | Key sources of available evidence | Key gaps in evidence |
|--|--|----------------------|
| | <p>angioedema with normal C1 esterase inhibitor. <i>World Allergy Organization Journal</i>, 15(1), p.100621.</p> <p>Grumach, A.S., Henriques, M.T., Bardou, M.L., Pontarolli, D.A., Botha, J. and Correa, M., 2022. Icatibant use in Brazilian patients with hereditary angioedema (HAE) type 1 or 2 and HAE with normal C1-INH levels: findings from the Icatibant Outcome Survey Registry Study. <i>Anais Brasileiros de Dermatologia</i>, 97, pp.448-457.</p> | |
| Consultation and involvement findings | None known | |
| Research | No pending research is known | |
| Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team | Through the Blood and Infection Programme of Care and its Clinical Reference Group structures supporting the policy working group with its expert knowledge regarding the epidemiology and treatment of bradykinin-mediated angioedema with normal C1 inhibitor. | |

7. Is your assessment that your proposal will support compliance with the Public Sector Equality Duty? Please add an x to the relevant box below.

| | Tackling discrimination | Advancing equality of opportunity | Fostering good relations |
|----------------------------|-------------------------|-----------------------------------|--------------------------|
| The proposal will support? | | | |

| | | | |
|--|---|---|---|
| The proposal may support? | | X | |
| Uncertain whether the proposal will support? | X | | X |

8. Is your assessment that your proposal will support reducing health inequalities faced by patients? Please add an x to the relevant box below.

| | Reducing inequalities in access to health care | Reducing inequalities in health outcomes |
|---|--|--|
| The proposal will support? | X | X |
| The proposal may support? | | |
| Uncertain if the proposal will support? | | |

9. Outstanding key issues/questions that may require further consultation, research or additional evidence. Please list your top 3 in order of priority or state N/A

| Key issue or question to be answered | Type of consultation, research or other evidence that would address the issue and/or answer the question |
|--------------------------------------|--|
| 1 | |
| 2 | |
| 3 | |

10. Summary assessment of this EHIA findings

This policy aims to make icatibant available for all adult patients with severe acute swellings due to bradykinin-mediated angioedema with normal C1 inhibitor who otherwise have no licensed treatment options. Routine approval as an intervention with appropriate oversight would allow equity of access for patients with a rare condition to potentially lifesaving treatment that is currently not routinely available to them. This policy is restricted to adults in line with the findings from the evidence review. However, as icatibant has a licenced indication in children aged two years and older for other conditions, NHS England's Policy 170001/P Commissioning

Medicines for Children in Specialised Services ([commissioning medicines children](#)) can be applied to this policy for children with bradykinin-mediated angioedema with normal C1 inhibitor aged two years and older if clinically eligible.

The use of icatibant would prevent acute hospital admissions and associated risk of death and intensive support needs and costs. Furthermore, it would prevent interruption to patients' daily activities of life, inability to work or attend school, or inability to look after their children or dependents. Patients can self-administer the subcutaneous treatment, which is usually a one-off dose, and treat acute swellings.

No adverse impacts of this proposal have been identified.

11. Contact details re this EHIA

| | |
|-------------------------------------|---------------------------------------|
| Team/Unit name: | Blood and Infection Programme of Care |
| Division name: | Specialised Commissioning |
| Directorate name: | Chief Finance Officer |
| Date EHIA agreed: | |
| Date EHIA published if appropriate: | |