

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## HEALTH TECHNOLOGY APPRAISAL PROGRAMME

### Equality impact assessment – Guidance development

#### STA Garadacimab for preventing recurrent attacks of hereditary angioedema in people 12 years and over [ID6394]

The impact on equality has been assessed during this appraisal according to the principles of the NICE equality scheme.

#### Consultation

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|--|--|
| 1.   | Have the potential equality issues identified during the scoping process been addressed by the committee, and, if so, how? |
| Identified at scoping:   |  |
| <ul style="list-style-type: none"><li>• Yes, the company noted during consultation that comparators Cinryze and Berinert are derived from human plasma, which some religious groups may be unwilling to be treated with. It further added that garadacimab is not directly extracted from human serum or plasma.</li><li>• A stakeholder also noted that a possible inequality that would exist is the availability within individual NHS Trusts to prescribe this medication.</li></ul> |  |



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|--|---|
| 2.   | Have any other potential equality issues been raised in the submissions, expert statements or academic report, and, if so, how has the committee addressed these? |
| Identified in submissions:   |   |
| <ul style="list-style-type: none"><li>• Young people [defined by NICE as people aged 12 to 17 years] have fewer HAE attacks than adults, which reduces their access to</li></ul> |   |



Technology appraisals: Guidance development

Equality impact assessment for the single technology appraisal of garadacimab for preventing recurrent attacks of hereditary angioedema in people 12 years and over

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Issue date: September 2025

treatment. HAE attack frequency increases with age. Access criteria for treatments that are based only on attack frequency may disadvantage young people, who can be significantly affected by HAE despite having attack frequencies below current access criteria.

The NICE committee noted that it makes recommendations within a technology's marketing authorisation and that garadacimab is indicated for prevention of recurrent attacks of hereditary angioedema in people aged 12 years and older. It also noted that the company positioned garadacimab in people 12 years and over having 2 or more attacks per month.

- Some comparators included in the decision problem, intravenous C1-INHs (Cinryze and Berinert), are derived from human plasma, which some religious groups may be unwilling to have. Garadacimab is an antibody produced by recombinant DNA technology. It is not directly extracted from human serum or plasma.

The NICE committee noted that lanadelumab is an existing alternative to C1-INHs, which is not from human plasma and that garadacimab would be another option that is not from human plasma.

3. Have any other potential equality issues been identified by the committee, and, if so, how has the committee addressed these?

None identified.

4. Do the preliminary recommendations make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?

No. The technology is not recommended.

5. Is there potential for the preliminary recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?

No. The technology is not recommended.

6. Are there any recommendations or explanations that the committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 4 or 5, or otherwise fulfil NICE's obligations to promote equality?

No

7. Have the committee's considerations of equality issues been described in the draft guidance, and, if so, where?

Yes, see section 3.19.

**Approved by Associate Director (name):** Ross Dent

**Date:** 24/06/2025

## Final draft guidance

1. Have any additional potential equality issues been raised during the second consultation, and, if so, how has the committee addressed these?

No new issues were raised in response to the consultation.

2. If the recommendations have changed after consultation, are there any recommendations that make it more difficult in practice for a specific group to access the technology compared with other

groups? If so, what are the barriers to, or difficulties with, access for the specific group?
<p>The recommendation changed after consultation: garadacimab is recommended as an option for preventing recurrent attacks of hereditary angioedema in people 12 years and over who are having 2 or more attacks a month.</p> <p>The committee noted young people tend to have a lower attack frequency than adults, and this may be below access criteria for current treatments. The committee noted that age is protected characteristic under the Equality Act 2010. However, the marketing authorisation for garadacimab is in people 12 years and over, and any recommendation by NICE must be within the marketing authorisation. The committee noted that the company positioned garadacimab in people having 2 or more attacks a month. The committee understood this positioning was consistent with NHS E's algorithm of commissioned treatment options for long-term prevention of hereditary angioedema attacks.</p>

3. If the recommendations have changed after consultation, is there potential for the recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?
No.

4. If the recommendations have changed after consultation, are there any recommendations or explanations that the committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 2 and 3, or otherwise fulfil NICE's obligations to promote equality?
No recommendations or explanations are needed.

5.	Have the committee's considerations of equality issues been described in the final draft guidance, and, if so, where?
	Yes, see section 3.19.

**Approved by Associate Director (name):** Ross Dent

**Date:** 04/09/2025