

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technologies evaluation programme

Equality impact assessment: Guidance development

MT323 gammaCore for cluster headache

The impact on equality has been assessed during this evaluation according to the principles of the [NICE Equality scheme](#).

Medical technology consultation document

1. Have the potential equality issues identified during the scoping process been addressed by the committee, and, if so, how?

- Self-administration of treatment with gammaCore needs manual dexterity and the ability to follow instructions and so may not be suitable for people with poor hand dexterity or cognitive impairment.
- gammaCore cannot be used by people with cochlear implants or pacemakers and has not been used in people who are pregnant, lactating or aged under 18 years.

The committee discussed use of gammaCore with the clinical experts and company and noted that treatment with gammaCore can be administered by a carer in section 4.9. The committee discussed that gammaCore is not suitable for some people, this is noted in section 4.7.

2. Have any other potential equality issues been highlighted in the sponsor's submission, or patient organisation questionnaires, and, if so, how has the committee addressed these?

No other equality issues were identified. Patient organisation statements and surveys highlighted the significant negative impact of cluster headaches and the importance of any treatment that reduces symptoms. This is noted in section 4.2.

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

No other equality issues were 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.

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.

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?

The committee may wish to consider research recommendations to explore the safety concerns of using gammaCore within the indications listed on page 6 of the [instructions for use](#).

7. Have the committee's considerations of equality issues been described in the medical technology consultation document, and, if so, where?

Sections 4.2, 4.7 and 4.9 of the medical technology consultation document.

Approved by Associate Director: Jo Holden

Date: 03 July 2019

Medical technology guidance document

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

No equality issues were raised during 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 access for the specific group?

No changes were made to the recommendations.

3. If the recommendations have changed after consultation, 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?

Not applicable

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?

Not applicable

5. Have the committee's considerations of equality issues been described in the medical technology guidance document, and, if so, where?

Sections 4.2, 4.8 and 4.10 of the medical technology guidance document

Approved by Programme Director: Mirella Marlow

Date: 03 July 2019