NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH TECHNOLOGY APPRAISAL PROGRAMME

Equality impact assessment – Guidance development

STA Mexiletine for treating the symptoms of myotonia in non-dystrophic myotonic disorders [ID1488]

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

Consultation

1.	Have any potential equality issues been identified during the scoping process (draft scope consultation and scoping workshop discussion), and, if so, what are they?
At the scoping workshop it was noted that although there is no evidence to suggest different prevalence among ethnicities, black and ethnic minority groups are underrepresented in the population currently treated with mexiletine. However this may be associated with the reluctance of some minority groups' reluctance to receive genetic testing for diagnosis.	

2.	What is the preliminary view as to what extent these potential equality issues need addressing by the committee?
It was noted in the workshop that access to the technology is not an issue and therefore other factors could be contributing to the underrepresentation of minority groups coming forward for treatment. This is not an issue that could be addressed by NICE through making adjustments to its process, nor could it be addressed in its recommendations.	

3.	Has any change to the draft scope been agreed to highlight potential equality issues?
No	

4.	Have any additional stakeholders related to potential equality issues been identified during the scoping process, and, if so, have changes to the matrix been made?
No	

Approved by Associate Director (name): ……Sheela Upadhyaya ……

Date: 22/05/2018

Final appraisal determination

(when an ACD issued)

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

Potential equality issues raised during consultation:

- *Lamotrigine has been proposed as a primary substitute by the committee. Feedback from our support group indicates that it has been helpful for some who were being treated concomitantly for depression and were able to combine that and myotonia treatment into one medication. However many have noted psychiatric side effects with lamotrigine as well. It is also affected by estrogen and must be monitored if women use birth control or hormone replacement therapy. And there are studies showing possibility of an increase in cleft palate or cleft lip if a woman becomes pregnant while taking lamotrigine.*
- *I hope disability from a rare disorder has been appropriately addressed*

- *It is a discrimination against the disabled to take away the drugs that allow them to lead a normal life*
- *The draft guidance if finalised unaltered will deny known effective treatment for those disabled by myotonia and prevent them from having a much fuller life than is possible.*
- *I do believe this is discrimination based on disability. By stating that the impact on quality of life is not significant enough to warrant the cost is discriminatory. The committee members have no idea what it is like to live with this condition 24 hours a day; wheelchair use should not be the criteria for the government's support. The alternative drugs mentioned are not going to be acceptable for many patients and will result in diminished quality of life for those who are currently taking the medication and thriving. Mexiletine is life-changing for so many patients, and removing it completely as one of the options for treatment is harsh and insensitive.*

How committee has addressed these:

- The committee noted that disability is a protected characteristic and that people with NDM have a disability that could make travel to regional neurology centres for treatment more difficult. The committee noted that any equalities issue relating to geographical access to treatment with NDM would already be realised as mexiletine is current standard practice. However, the committee concluded that this potential equality issue could not be addressed in the guidance recommendations.
- The committee noted that there are possible sex-based differences in alternative treatment suitability. For example, an increased risk of major birth defects in pregnancy have been seen with phenytoin, and changes in the body during pregnancy may affect lamotrigine levels or therapeutic effect. However, the committee noted that mexiletine should be avoided during pregnancy (so recommending it for a specific sub-group, people who are pregnant, would not be appropriate). It concluded that this potential equality issue could not be addressed in the guidance recommendations.

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?

No, recommendation should result in stable supply of a form of mexiletine for all NDM treatment centres, so should avoid potential unfair geographical access.

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.	

5.	Have the committee's considerations of equality issues been described in the final appraisal determination, and, if so, where?
Yes, in sections 3.18 and 3.19.	

Approved by Associate Director (name): …Linda Landells……

Date: 26 October 2021