NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

DIAGNOSTICS ASSESSMENT PROGRAMME

Equality impact assessment – Early value guidance development

Early value assessment: Genedrive MT-RNR1 ID Kit for detecting a genetic variant to guide antibiotic use and prevent hearing loss in babies

Consultation

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

   Potential equality issues were discussed both in the scoping workshop on the 10 August 2022 and in the assessment subgroup meeting on the 25 August 2022.

   The following potential equality issues were identified during scoping:

   - The PharmGKB allele frequency table for the *MT-RNR1* gene reports that frequencies of the m.1555A>G variant differ by ethnic family background, so testing may be particularly beneficial in some groups.
   - Tests that do not detect all relevant variants in the *MT-RNR1* gene could disproportionately affect different ethnic groups based on the prevalence of these alleles.
   - Mothers from a minority ethnic family background or those with a lower socioeconomic status may have an increased risk of early-onset neonatal infection and may be more likely to need treatment with antibiotics.
   - The acceptability and consent for genetic testing may differ according to religious or philosophical beliefs.

   The committee considered that the prevalence of the m.1555A>G variant varies between different ethnic family backgrounds. The committee said that further evidence generation should be done in centres with patients from diverse ethnic family backgrounds. The committee also considered equity of access and noted that it would be

necessary to ensure that the test was implemented in a wide range of geographical regions, to include patients from various socioeconomic groups (see section 3.2). It recommended that data is collected in a range of centres, including smaller non-specialist centres and those with patients from different ethnic backgrounds (see recommendation 1.1). The committee considered that other variants in the *MT-RNR1* gene are also associated with a risk of aminoglycoside induced hearing loss. It said that babies that test negative for the m.1555A>G variant but still go on to develop hearing loss should be followed up with laboratory testing to determine if they have had a false negative result or have a different *MT-RNR1* variant.

2. Have any other potential equality issues been raised in the external assessment report, and, if so, how has the Committee addressed these?

   No other potential equality issues have been raised in the external assessment report.

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

   No other potential equality issues have been identified by the committee.

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?

   N/A

7. Have the Committee's considerations of equality issues been described in the early value guidance document, and, if so, where?

   Yes. The Committee's considerations of the prevalence of the m.1555A>G variant in different ethnic groups and equity of access to people from different geographical regions and socioeconomic groups is in section 3.2. The committees evidence generation considerations in relation to the differences in prevalence between different ethnic groups are in section 3.11. Evidence generation considerations around equity of access are in section 3.13. Recommendation 1.1 states that data should be collected in a range of centres, including smaller non-specialist centres and those with patients from different ethnic backgrounds. The committee's considerations of other variants in the *MT-RNR1* gene that are associated with a risk of aminoglycoside induced hearing loss are in section 3.7.

   Recommendation 1.2 highlights that healthcare professionals should tell parents about the possible implications of positive test results for their baby and their family at an appropriate time, and give support and information.

Approved by Programme Director (name): Sarah Byron

Date: 01/02/2023

Early value guidance document

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

   No additional equality issues have been 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, or difficulties with, access for the specific group?

No

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?

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?

N/A

5. Have the Committee's considerations of equality issues been described in the early value guidance document, and, if so, where?

The Committee's considerations of the prevalence of the m.1555A>G variant in different ethnic groups and equity of access to people from different geographical regions and socioeconomic groups is in section 3.2. The committees evidence generation considerations in relation to the differences in prevalence between different ethnic groups are in section 3.11. Evidence generation considerations around equity of access are in section 3.13. The 'Managing the risk of early access' box (see pages 2 to 3 of the early value guidance document) states that data should be collected in a range of centres, including smaller non-specialist centres and those with patients from different ethnic and socioeconomic backgrounds. The committee's considerations of other variants in the MT-RNR1 gene that are associated with a risk of aminoglycoside induced hearing loss are in section 3.7.

Recommendation 1.2 highlights that healthcare professionals should tell parents about the possible implications of positive test results for

their baby and their family at an appropriate time, and give support and information.

Approved by Associate Director (name): Rebecca Albrow

Date: 09/03/23