

**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**TECHNOLOGY APPRAISAL PROGRAMME**

**Equality impact assessment – Scoping**

**TA Saproterin for treating phenylketonuria**

**Batch 63**

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

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?

During the scoping process, it was highlighted that some people have particular difficulties adhering to conventional dietary management of phenylketonuria (PKU), including people with physical and mental health difficulties and disabilities, people with particular housing or caring arrangement, and people from particular family origins (including people with Irish Traveller family origins and people whose first language is not English).

During the scoping process it was also highlighted that the carer burden of PKU falls particularly upon women, as primary carers for children with PKU. The burden of managing the restrictive dietary requirements was emphasised.

It was noted that sapropterin is currently funded by NHS England for some people who are pregnant, and that it may have particular benefits in this group.

Consultees noted that people who are treated late or not treated for their PKU, and people who are lost to follow up, may have particular challenges.

2. What is the preliminary view as to what extent these potential equality issues need addressing by the Committee?

It is possible that sapropterin may have particular benefits in people who are unable to adhere to conventional dietary therapy. Where this is influenced by protected characteristics (such as disability or family origin), this may represent an equality issue within the Equality Act. The committee should consider any equality implications accordingly. For other factors, such as caring arrangements, there may be no equality issues within the Act but the committee may nevertheless give consideration to such factors.

Household disparity in gender roles, and therefore relative carer burden, is not an equality issue that could be addressed within a technology appraisal. If appropriate, the committee may consider the impact of the condition and treatment on the health of carers and the costs of care, as specified in the scope and the [Guide to the methods of technology appraisal](#).

Sapropterin's marketing authorisation permits treatment during pregnancy in specified circumstances, and may therefore be considered during the appraisal for these circumstances. If so, consideration should be given to any equality implications.

The marketing authorisation does not permit treatment during breastfeeding, and so cannot be considered by the committee.

People who are treated late, untreated or lost to follow-up are not expected to represent an equality issue that can be addressed within a technology appraisal.

3. Has any change to the draft scope been agreed to highlight potential equality issues?

The scope specifies that, if evidence allows, consideration may be given to people with childbearing potential and people whose phenylalanine levels are not adequately controlled by diet (including those who are unable to adhere to the required diet). It also specifies that if so, the committee will consider any equalities implications of its considerations.

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?

It is noted that PKU may have a relatively high prevalence in people with Irish Traveller family origins, and that conventional dietary management may be particularly difficult in this group. Organisations representing this group have therefore been added to the matrix.

**Approved by Associate Director (name):** .... Janet Robertson

**Date:** 28 May 2020