Equality and Health Inequality Assessment

# 1. Name of the policy, project, or programme

Refinement of Highly Specialised Technologies Routing Criteria

# 2. Directorate or team

Clinical Directorate

# 3. Details of the person responsible for the EHIA (EHIA Owner)

Kay Nolan, Head of Prioritisation and Surveillance

# 4. Aims, purpose and outcomes

## What are the main aims, objectives and intended outcomes?

The aim of the HST routing criteria is to act as the framework for decision making regarding the routing of technologies to the HST programme or Technology Appraisal programme. The routing criteria should support decision making in line with the HST vision and strike a balance between the desirability of supporting access to treatments for ultra rare diseases and the associated reduction in overall health gain across the NHS.

The purpose of the proposed refinement to the criteria is to:

* Enhance the criteria to be more explicit and objective without changing the essence or intent
* Provide additional guidance and clarity on the application of criteria to improve the transparency of routing decisions
* Neither increase nor decrease the number of medicines routed to the HST programme
* Promote efficient decision-making for HST routing decisions and reduce the need for further clarification.

## How does this fit in with the objectives of NICE?

This work supports the strategic objective of timely and usable advice.

## How does it relate to other NICE policies or activity?

The proposed refinements will replace the existing HST routing criteria detailed in NICE-wide topic prioritisation: the manual. The criteria will be used by the Prioritisation Board to determine the routing of technologies under consideration for the Highly Specialised Technologies programme and associated process and methods for evaluation.

## Who will benefit from it?

Users of our guidance will benefit from a transparent approach to the routing of technologies to the HST programme. This will mean that all stakeholders including manufacturers and patient groups should have more predictability in the routing decision making process for technologies being considered as an HST. It is hoped that this will mean that routing decisions will be more efficient with clear rationale as to why a technology is routed to HST or technology appraisal programmes.

## What are the main activities involved in implementation?

Implementation steps will include updating the Topic Prioritisation manual to include refined criteria and the development of a checklist for the application of the criteria. There will also be training of staff across technical teams at NICE and prioritisation board members to support the effective implementation of the refined criteria.

# 5. Engagement and involvement

This EHIA has been developed by the team reviewing and refining the HST routing criteria. We will invite comments on the EIA as part of the consultation on the refined criteria so that it can be developed and considered further.

# 6. Other evidence and information considered

A consultation on the refinements will be undertaken with all stakeholders to seek their views on the proposals. As part of this consultation process, we will seek views as whether any of the proposals raise equalities or health inequality issues.

# 7. Potential impact and mitigation

Potential impact and mitigation for protected characteristics or wider determinants of health

| Protected characteristic or wider determinant of health | Comments | Mitigation if appropriate |
| --- | --- | --- |
| Age | Ultra rare diseases have challenges in gathering information on the aetiology and epidemiology by the nature of them being very rare. Some ages may be indirectly disadvantaged due to uncertainty in quantifying concepts in the definitions in the proposals. Conversely, this uncertainty in aetiology and epidemiology may also work to advantage some conditions impacting certain age groups potentially younger ages. | Completed HST checklists will be audited for insight into the application of the proposed definitions, for example to see if some definitions are consistently challenging to complete for certain age groups. |
| Disability  | Disabled people are likely to be the largest group affected by the topics being considered for HST guidance. Many people living with ultra rare diseases would be protected under the Equality Act 2010. The aim of the HST routing decision, regardless of the decision outcome, is to promote timely evaluation of technologies which should improve access to effective treatments to modify disease progression or improve symptoms of the condition where current treatment is unsatisfactory. Therefore, the HST programme by its very nature positively discriminates in favour of ultra rare (often disabling) conditions.The proposed refinements should not impact on this. | N/A |
| Race or ethnicity  | None identified. | N/A |
| Gender reassignment  | None identified. | N/A |
| Marriage and civil partnership  | None identified | N/A |
| Pregnancy and maternity  | None identified. | N/A |
| Religion and belief  | None identified. | N/A |
| Sex | The definition for criterion 1 defining point prevalence operates at the whole population level. If a disease is over or under identified in a protected group this may impact differently on the assessment of the criteria being met.This refinement is no different to the existing HST criteria.  | It is anticipated that if implemented the proposals would positively impact on populations with protected characteristics in that they may be more likely to be under-represented in the numerator estimation. |
| Sexual orientation  | None identified. | N/A |
| Socioeconomic status | None identified. | N/A |
| Inclusion health and vulnerable groups | None identified. | N/A |

# 8. EHIA sign off

EHIA Owner: Jonathan Benger, Deputy Chief Executive, Chief Medical Officer, Clinical Directorate

Date: December 2024.