Board meeting

11 December 2024

Refinement of highly specialised technologies (HST) routing criteria

Purpose of paper

For approval

Board action required

1. The Board is asked to:
   * Support the proposed refinement for the current HST criteria
   * Delegate sign-off of any changes required to the consultation materials following the Board meeting to the Chief Executive
   * Agree that we proceed with the external stakeholder consultation on 19 December 2024

Brief summary

The current HST routing criteria were published in 2022 and provided a significant improvement to the previous criteria; however, criticisms remain which contribute to timeliness of evaluations and potentially delays to effective treatments for patients. The current proposed revisions aim to enhance the predictability and transparency of the application of the HST routing criteria, while maintaining the intent of the HST vision. This paper seeks agreement to proceed to the external stakeholder consultation on 19 December 2024 until 30 January 2025.

Board sponsor

Professor Jonathan Benger, Chief Medical Officer, Deputy Chief Executive and interim Director for the Centre for Guidelines

Introduction

1. This paper details the proposed consultation paper for the routing criteria for Highly Specialised Technologies.

To accompany the consultation document there will also be a pack of supplementary material detailing:

* 1. Retrospective impact analysis of previous decisions
  2. Equality Impact Assessment
  3. Frequently Asked Questions
  4. Information providing rationale for the refinement and key differences between existing and proposed criteria

The Board to provide feedback on the consultation paper and approve the paper for consultation in December.

Background

The current HST routing criteria were published in 2022 and provided a significant improvement to the previous criteria; however, criticisms remain which contribute to timeliness of evaluations and potentially delays to effective treatments for patients. The current proposed revisions aim to enhance the predictability and transparency of the application of the HST routing criteria, while maintaining the intent of the HST vision.

The revisions have been developed by a taskforce of staff from Clinical Directorate and Medicines Evaluations team. The proposals have been discussed by a cross-NICE group who have held two round tables to feedback on proposals. There have been two discussions with NICE Board and broader external engagement with key groups including, Rare Disease Advisory Group, current and former HST chairs, the Association of the British Pharmaceutical Industry (ABPI), BioIndustry Association (BIA), Department of Health and Social Care, and NHS England in addition to a well-attended webinar.

The key changes to the existing criteria are:

* 1. Clear mapping to the concepts in the HST vision
  2. Addition of definitional statements to enhance predictability and transparency in the application of the criteria.

A retrospective analysis of previous routing decisions under the existing criteria has been undertaken. This resulted in 2 discordant decisions between existing and proposed criteria (one in each direction). This analysis supports the aim of cost neutrality of criteria refinement.

Finance / HR / legal implications.

We have consulted Beachcroft for legal advice and amended proposals accordingly.

Cross organisational impact

N/A.

Risk assessment

We have undertaken a retrospective HST routing decision analysis to consider the impact of applying the new criteria to technologies assessed for HST. This will be included as a supporting document to the consultation paper.

Risk assessment table.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Risk | Current mitigation, controls, and assurance | Current rating: Impact | Current rating: Likelihood | Current rating: Score | Further actions to strengthen mitigations and achieve the target score.  (include due dates) | Target rating: Impact | Target rating: Likelihood | | Target rating: Score |
| The consultation receives a lot of negative feedback related to the proposed refinement of the HST criteria. | We have engaged extensively with external stakeholders, from industry, patients’ groups, NHS England and Department of Health and Social Care.  We have conducted a comprehensive retrospective routing decision analysis to consider the impact of applying the new refined criteria to past decisions that shows neutral impact.  We will provide supporting information to help rationalise changes within the refined criteria. | 3 | 4 | 12 | Following the consultation, we will carefully consider the feedback we receive from our stakeholders and the publish thematic comments addressing any issues that are raised during the consultation.  We will engage with key stakeholders on our assessment of the stakeholder feedback | 3 | | 3 | 9 |

Board action required.

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  3. Agree that we proceed with the external stakeholder consultation on 19 December 2024

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