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TO HST, OR NOT TO HST

– that is the question

2026 update

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EXECUTIVE SUMMARY

The National Institute of Health and Care Excellence (NICE) highly specialised technologies (HST) route offers manufacturers a substantially more generous cost-effectiveness threshold of up to £300,000 per quality-adjusted life-year (QALY), compared with the standard single technology appraisal (STA) threshold of £25000–35000/QALY. Given this, the HST route is highly attractive to manufacturers of treatments for ultra-rare diseases. However, it is expressly designed for exceptional circumstances and access has always been limited.

In April 2025, NICE revised its HST routing criteria – the latest in a series of refinements since the programme's inception in 2013 – with the aim of improving the predictability and transparency of routing decisions by introducing clearer definitional statements for the four qualifying criteria. To explore how these refined criteria are being applied in practice, Cogentia has conducted an updated analysis of HST routing decisions made under the new criteria.

Of the nine appraisals assessed under the revised criteria between April 2025 and May 2026, only one was routed to HST. The remaining eight were directed to the standard STA process.

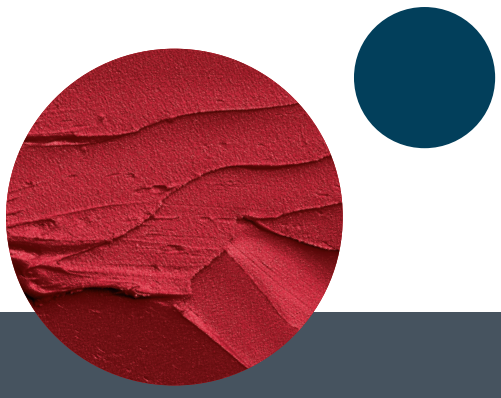
Our findings suggest that the HST route might be becoming less attainable under the refined criteria. Stakeholder research presented at ISPOR Europe 2025 indicates a variation in how NICE and manufacturers interpret key concepts such as "substantial negative impact" and "substantial additional benefit." Although the impact assessment for the criteria refinement from NICE projected no net change in routing rates, early evidence points to a tightening in practice.

Given the increasing stringency of the HST routing process, early and thorough preparation is essential. Based on our analysis, manufacturers should invest in early, targeted evidence generation spanning clinical expert input, patient advocacy engagement, UK registry data and focused literature reviews to substantiate prevalence estimates, disease burden and unmet need. Further, demonstrating the novel mechanism of action of the medicine and a thorough understanding of the existing treatment landscape will be essential to a compelling HST routing case.

INTRODUCTION

Health technology assessment in England is conducted by the National Institute of Health and Care Excellence (NICE), which makes recommendations on medicines that can be considered for routine commissioning by NHS England. Most technologies are appraised through a single technology appraisal (STA) process; however, for a small subset of technologies treating very rare, severe conditions, there is an alternative route – the highly specialised technology (HST) evaluation.

Compared with an STA, for which the incremental cost-effectiveness ratio (ICER) threshold is £25000–35000 per quality-adjusted life-year (QALY) gained (since April 2026), appraisal via HST permits a far more generous ICER of £100,000–300,000, depending on the number of undiscounted QALYs gained.[1] Other benefits of the HST process include a perceived willingness to accept greater uncertainty in the evidence package by the HST committee and a consideration of the impact beyond direct health benefits, including taking a societal perspective. Further, owing to the relative lack of evidence available for ultra-rare conditions, the patient and carer perspective is given greater focus in the HST process. Given these reasons, the HST route is highly attractive to manufacturers. The degree of public and parliamentary interest in treatment options for patients with rare diseases is perhaps best illustrated by the NICE HST process having been discussed in the UK Parliament on numerous occasions.



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However, NICE is acutely aware that recommending a technology via HST results in the National Health Service (NHS) allocating resources that would otherwise have been used on activities that would be expected to generate greater health benefits. As a result, the HST programme is designed to be used only in exceptional circumstances. Indeed, compared with 1167 published STAs, only 35 HSTs have been published at the time of writing.

In 2024, Cogentia published a white paper entitled "To HST or not to HST – that is the question", exploring the application of HST eligibility criteria, and aiming to understand the decision-making process and the key contributing factors to a routing decision.[3]

Our analysis found that of 23 topics referred for a topic selection decision to determine HST eligibility, four (17.4%) were successful in achieving an HST routing. Of the four criteria required to be met to achieve HST routing, the success rate ranged from 45.7% to 76.1%.

Since our white paper, the HST criteria have been revised once again, with Jonathan Benger, NICE Chief Medical Officer at the time, stating that the reason for this change was "to help ensure fairer and more predictable decisions".[4] Following this, some stakeholders raised concerns as to whether the additional clarity and removal of ambiguity might negatively affect the number of technologies routed to HST. As our original white paper demonstrated, it is the ability at times to provide discretion (eg when other criteria are clearly met) that allowed some technologies to achieve HST routing.

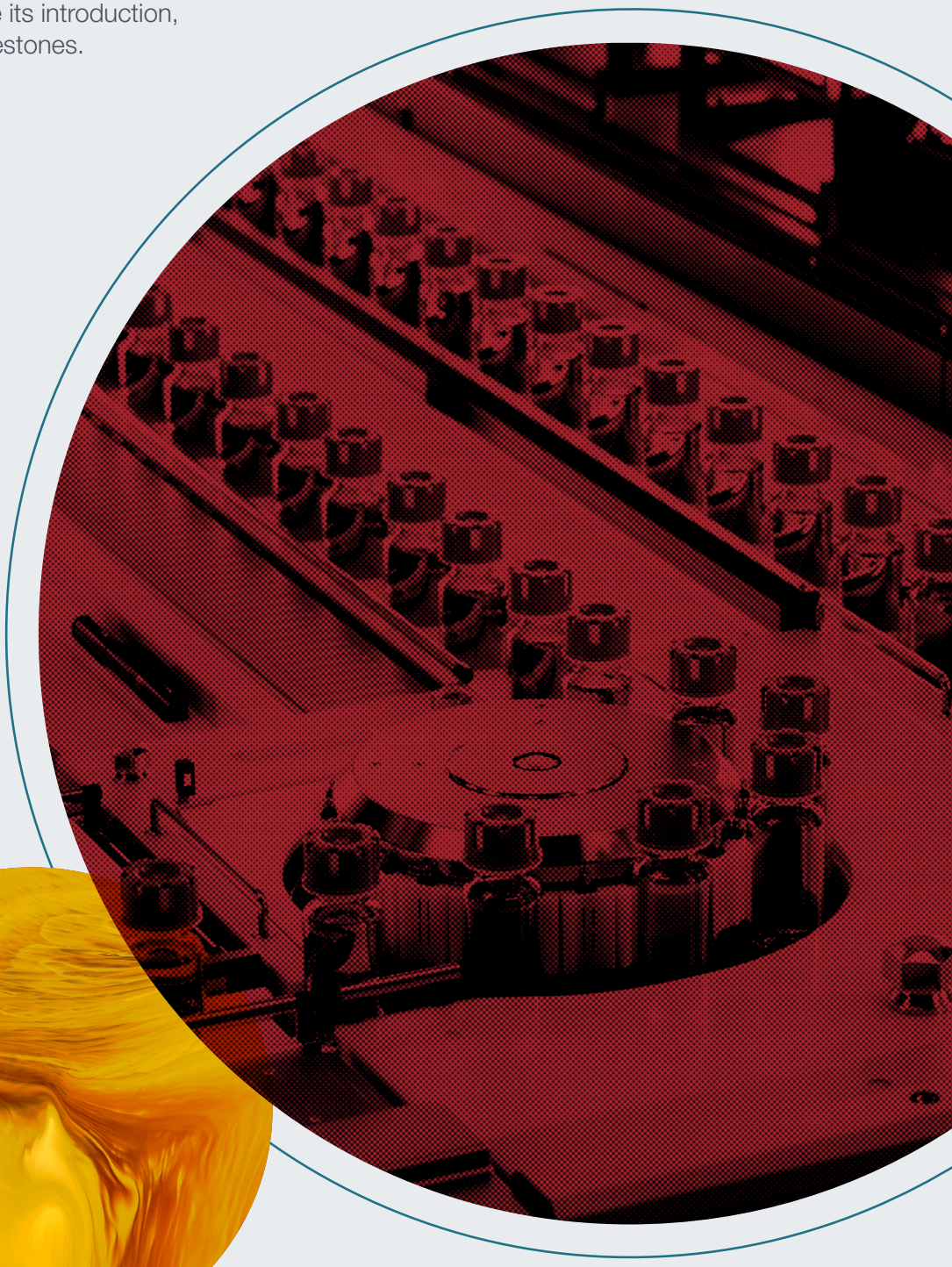
To pursue this hypothesis, and to explore more generally how the new HST criteria are being applied, we present an updated analysis, covering the time period from April 2025 to May 2026.

> *"The HST programme is designed to be used in exceptional circumstances, to evaluate technologies for ultra-rare diseases that have small numbers of patients, and where there are significant challenges for research and difficulties in collecting evidence because of the rarity of the disease"*
>
> – NICE[2]

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BRIEF HISTORY OF HST

The HST route was introduced by NICE in April 2013, taking over responsibility from the Advisory Group for National Specialised Services. Figure 1 presents a timeline of the HST route since its introduction, highlighting some of the key milestones.



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Figure 1: Key milestones for HST

2013
May 2013
NICE introduces HST route

2014

2015
January 2015
HST1 eculizumab for the treatment of aHUS is published. Eculizumab is recommended with no PAS

2016

2017
April 2017
NICE introduces a willingness to pay threshold of £100,000–£300,000 per QALY
June 2017
HST5 eligustat for type 1 Gaucher disease recommended

2018
February 2018
HST7 sees the first gene therapy (strimvelis) recommended via HST with no PAS

2019
August 2019
HST10 patisiran for hATTR amyloidosis recommended

2020

2021
January 2022
NICE methods update refines the HST criteria from seven to four

2022
May 2022
HST20 selumetinib for type 1 neurofibromatosis recommended

2023
July 2023
HST27 results in the first negative HST recommendation

2024
January 2024
HST30 sebelipase alfa for Wolman disease recommended

2025
April 2025
NICE refine HST routing criteria to support "more consistent, predictable and transparent decisions"

2026
March 2026
HST35 pegzilarginase for arginase-1 deficiency recommended

aHUS, atypical haemolytic uraemic syndrome; hATTR, hereditary transthyretin amyloidosis; HST, highly specialised technology; NICE, National Institute of Health and Care Excellence; PAS, patient access scheme; QALY, quality-adjusted life-year

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EVOLUTION OF THE HST ROUTING CRITERIA

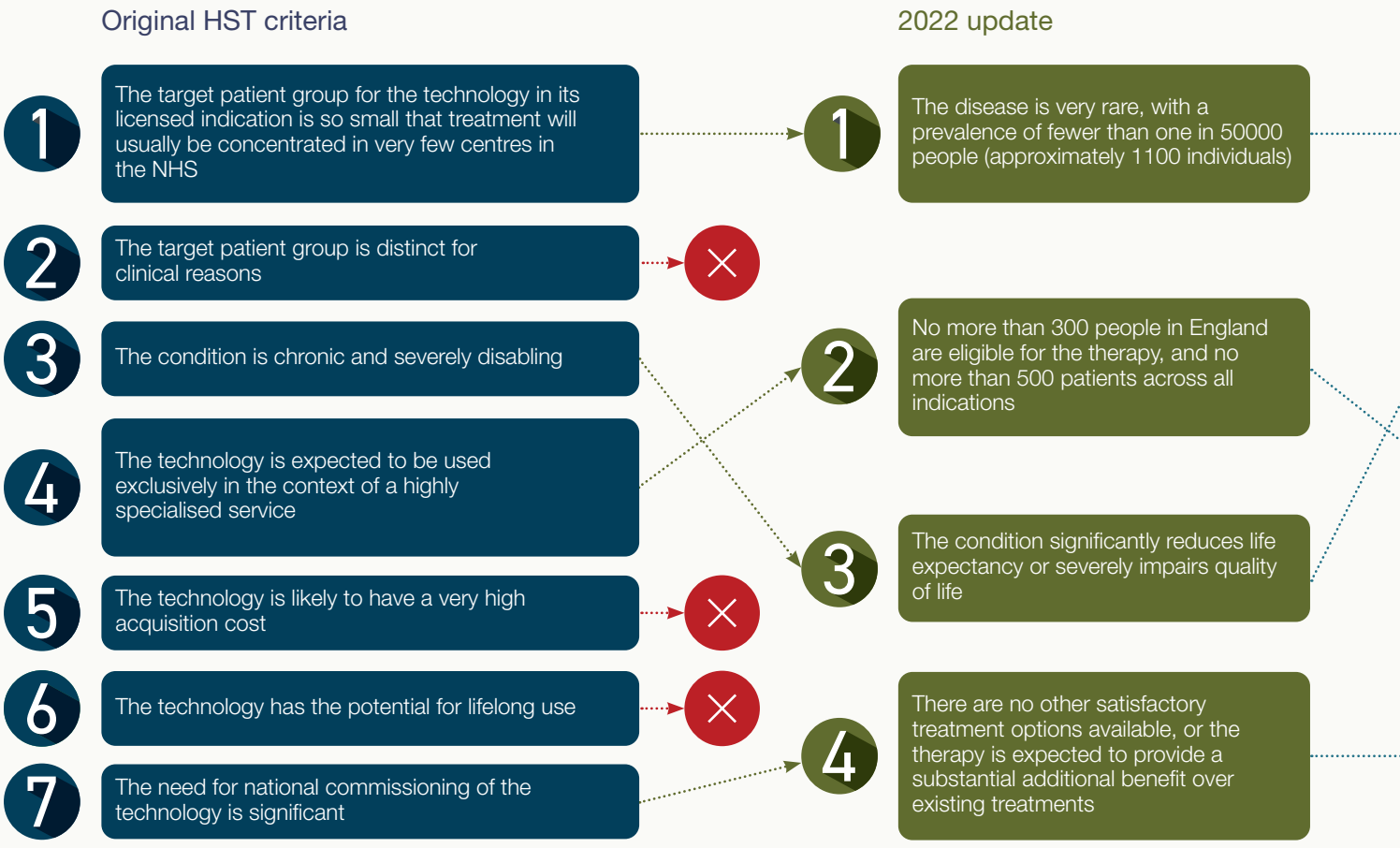
When the NICE HST route was first introduced in 2013, interventions had to satisfy seven criteria to qualify. These criteria focused on the epidemiology of the rare disease, its debilitating nature and the urgent need for new treatment options in an otherwise underserved patient population. Although the criteria have evolved over the 13 years since the inception of the HST programme, the broader vision of NICE has remained consistent, with the underlying requirements remaining relatively unchanged, even if the precise wording of the selection criteria has developed.

In 2022, NICE revised the original criteria, notably removing the expectation for the technology to have a very high acquisition cost.[1] It is unsurprising that NICE removed this criterion given the tendency of pharmaceutical companies to view the HST route as a vehicle to achieve higher drug prices through its higher willingness to pay threshold, rather than its intended purpose of recognising the inherent uncertainty in appraising for patients with ultra-rare diseases.

In response to concerns around speed of decision-making, NICE proposed further refinements to the HST routing criteria in December 2024 to improve predictability while maintaining the principle that the HST route should remain reserved for exceptional cases involving ultra-rare, severe and debilitating diseases. The revision more clearly mapped the criteria to the overarching vision of NICE for HST, and introduced new definitional statements to enhance consistency and transparency in their application. The NICE board approved these updates in March 2025, and the criteria have been used for routing decisions from April 2025 onward.[2]

A summary of the evolving HST criteria is provided in Figure 2.

Figure 2: NICE methods update – HST criteria changes



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2025 refinement

1. The disease is ultra-rare and debilitating
2. The technology is an innovation for the ultra-rare disease
3. No more than 300 people in England are eligible for the technology in its licensed indication, and the technology is not an individualised medicines
4. The technology is likely to offer substantial additional benefit for people over existing established clinical management, and the existingestablished clinical management is considered inadequate

HST, highly specialised technology; NICE, National Institute of Health and Care Excellence; NHS, National Health Service

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OBJECTIVES OF THE ANALYSIS

Following publication of the four new criteria in April 2025, Cogentia has conducted a detailed analysis of the available HST topic selection decisions made by the NICE prioritisation board. Appraisals were identified through review of the NICE prioritisation board decisions for 2025 and 2026.

At the time of writing, there have been nine appraisals routed using the refined HST checklist, starting with zanidatamab for human epidermal growth factor receptor 2 (HER2)-positive advanced biliary tract cancer (ID6388), for which the routing decision was published in May 2025.

THE OBJECTIVES OF THIS ANALYSIS

1. Establish the key contributing factors to treatments being routed via HST or STA
2. Understand better the topic selection decision-making process, including the interpretation of each criterion and the use of external sources to inform it
3. Provide recommendations to manufacturers with orphan medicines that they believe might be eligible for HST routing

ANALYSIS OF NICE HST ROUTING DECISIONS USING REFINED CRITERIA

A high-level summary of the nine appraisals that have undergone a HST routing decision using the new April 2025 criteria is presented in Table 1. Of these nine appraisals, only one was routed to HST and the remainder were routed to the standard STA process.

Having summarised the outcomes for technologies considered by the NICE prioritisation board, we then reviewed the supporting documentation for each appraisal, assessing the rationale of whether each HST criterion was met or not.

The outputs of this analysis are illustrated in Figure 3.



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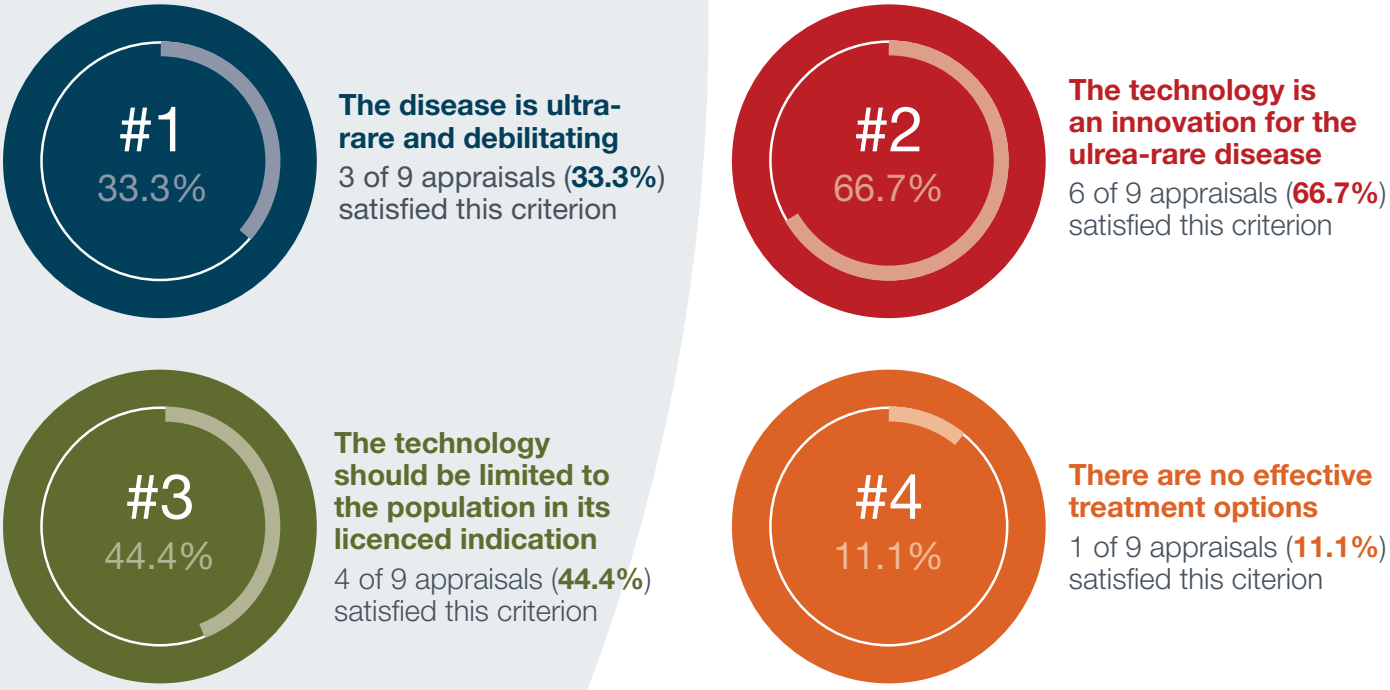
Table 1: Summary of NICE prioritisation board decisions per HST criterion

Topic ID	Technology	Indication	HST or STA?	Routing decision published	Criterion #1 Ultra-rare and debilitating	Criterion #2 Innovation	Criterion #3 Limited to licenced population	Criterion #4 No effective alternatives
ID6388	Zanidatamab	HER2-positive advanced biliary tract cancer	STA	May 2025	✘	✘	✔	✘
ID6484	Doxecitine–doxribtimine	Thymidine kinase 2 deficiency	HST	August 2025	✔	✔	✔	✔
ID6453	Nirogacestat	Desmoid tumours	STA	August 2025	✘	✔	✔	✘
ID6488	Vosoritide	Achondroplasia for people aged 4 months and over	STA	August 2025	✘	✔	✘	✘
ID1627	Histamine dihydrochloride with interleukin-2	Maintenance treatment of acute myeloid leukaemia	STA	August 2025	✘	✘	✘	✘
ID6557	Tovorafenib	Paediatric low-grade glioma with *BRAF* fusion or rearrangement or *BRAF* V600 mutation	STA	November 2025	✘	✔	✔	✘
ID6593	Plozasiran	Familial chylomicronaemia syndrome	STA	November 2025	✔	✔	✘	✘
ID6585	Olezarsen	Familial chylomicronaemia syndrome	STA	November 2025	✔	✔	✘	✘
ID6618	Mirdametinib	Plexiform neurofibromas	STA	March 2026	✘	✘	✘	✘

Analysis was performed in May 2026

HER2, human epidermal growth factor receptor 2; HST, highly specialised technology; NICE, National Institute of Health and Care Excellence; STA, single technology appraisal

Figure 3: Summary of NICE prioritisation board decisions for the four HST criteria using the latest April 2025 refinement



Analysis was performed in May 2026

HST, highly specialised technology; NICE, National Institute of Health and Care Excellence

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NICE PRIORITISATION BOARD DECISIONS, RATIONALE AND SOURCES PER CRITERION



Criterion 1: The disease is ultra-rare and debilitating

This criterion consolidates two elements from the previous 2022 HST checklist: the requirement that the disease must be very rare (formerly criterion 1) and that the disease is debilitating (formerly criterion 3). During consultation on the revised criteria, stakeholders noted the shift in NICE terminology from "rare" to "ultra rare", expressing concern that this implied more stringent eligibility requirements.[5] NICE clarified, however, that the underlying prevalence threshold remains unchanged and that the revised terminology is intended to better reflect the broader rare disease landscape.

In relation to the requirement for a patient population of 1100 individuals or fewer, stakeholders highlighted that the limited evidence base for ultra-rare diseases can make prevalence estimation challenging, and suggested that NICE should allow some flexibility in applying this threshold.[5] Although NICE acknowledged these challenges, it maintained that introducing such flexibility would contradict the objective of the refinement in increasing transparency and predictability of routing decisions.

Stakeholders also raised concerns about the interpretation of "exceptional negative impact", questioning what evidence would be required to meet this criterion.[5] In addition, they emphasised that the impact of ultra-rare, debilitating diseases extends beyond the individual patient, often affecting carers, families and wider society over the long term. NICE responded that the assessment of "substantial negative impact" would necessarily vary across conditions owing to differences in clinical presentation and disease burden, and would therefore involve an element of judgement. Notably, NICE recognised the broader impact on carers and families, confirming that these effects are considered within the definition of "exceptional negative impact".

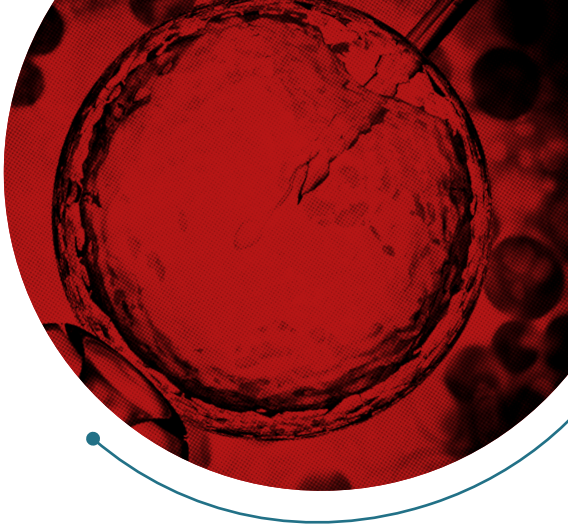
Of the nine routing decisions made using the refined criteria, only three appraisals were considered to meet criterion 1. Given that criterion 1 is now multi-faceted, having both a prevalence component and a quality-of-life component, which of these is making it difficult to achieve?

In determining point prevalence, NICE typically drew on data from relevant charities and the Office for National Statistics, although published literature and horizon scanning briefing notes were also used in some cases. Interestingly, despite prevalence being a relatively objective measure, agreement on prevalence estimates was not always observed between NICE and manufacturers.

Further, there was variability in how NICE assessed the debilitating nature of each disease. In some instances, the prioritisation board placed particular emphasis on published evidence, including retrospective natural history studies and patient perspective research. In others, the published routing decisions did not cite any evidence sources underpinning judgements on disease burden, which appears to be inconsistent with the stated aim of NICE of improving transparency in routing decisions.

Although stakeholder comments on disease burden were considered in one routing decision (ID6484), it is notable that inputs from patient advocacy groups and clinical experts have not been more consistently incorporated in applying this criterion. Given the well-understood paucity of evidence for many ultra-rare diseases, and the true extent of disease burden often being understood best through clinical experience, it might have been reasonable to expect more systematic consideration of clinician and patient perspectives in the application of this criterion.

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#2

Criterion 2: The technology is an innovation for the ultra-rare disease

First introduced as part of the 2025 refinement to the HST criteria, this criterion reflects the vision of NICE that the HST programme should encourage innovation and research into ultra-rare diseases for which there is poor provision in the NHS, rather than the use of repurposed technologies or extensions of an indication from another population or disease.

When first announced, stakeholders considered that this criterion was restrictive and called for its removal from the routing assessment; however, despite these concerns, NICE reaffirmed its commitment to this criterion.

> *We do not believe a repurposed technology, or a significant extension of an existing licensed indication, is innovation in technology that warrants an exceptional departure from the usual ICER used in NICE evaluations*
>
> – NICE[5]

Of the four criteria, this was the most frequently met, with the prioritisation board considering this fulfilled in 66.7% of appraisals. Notably, at the time of writing, it was the only criterion deemed to be met in more than half of the appraisals reviewed by the NICE prioritisation board under the refined framework.

In applying this criterion, the NICE prioritisation board placed considerable emphasis on technologies demonstrating novel and improved mechanisms of action compared with existing treatment options. This was particularly relevant in cases when existing treatments are primarily supportive rather than addressing the underlying pathophysiology. The value of innovative technologies was often supported by horizon-scanning evidence and clinical expert opinion. Additionally, orphan designation was explicitly recognised and highlighted by the prioritisation board when applicable.

Interestingly, in the appraisal of zanidatamab for HER2-positive advanced biliary tract cancer (ID6388), both the company and external assessment group documentation included “promising innovative medicine” (PIM) in their lists of abbreviations. This potentially suggests that zanidatamab might have received PIM designation from the Medicines and Healthcare products Regulatory Agency (MHRA), although explicit confirmation appears to be redacted in the publicly available documents on the NICE website. In contrast, the NICE prioritisation board concluded that zanidatamab did not meet its criterion for innovation under the HST checklist, citing its mechanism of action and the availability of other therapies for the target population. This alludes to a potential mismatch in definitions of what is considered to be innovative by NICE compared with the MHRA.

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#3

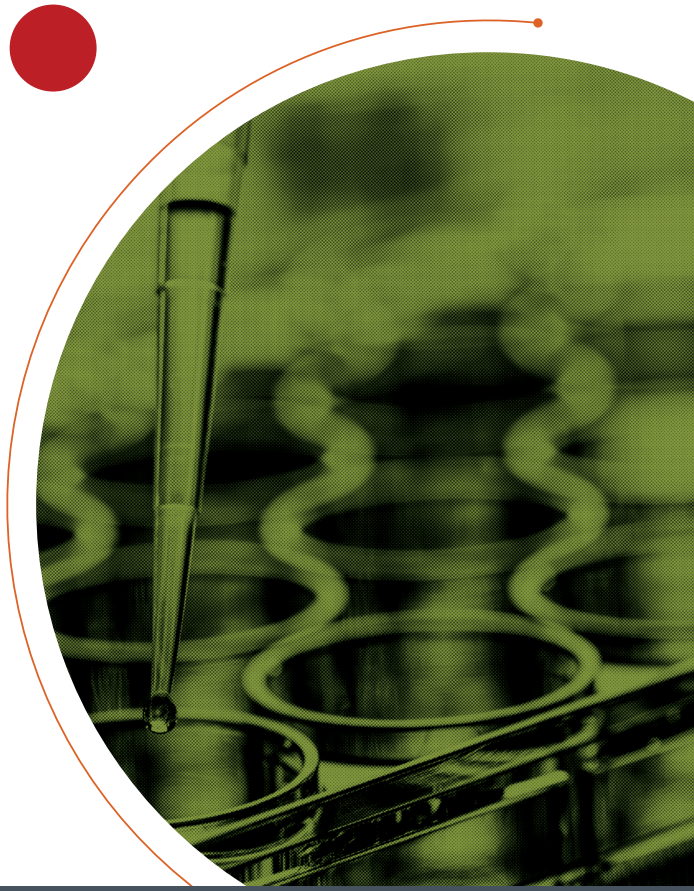
Criterion 3: The technology should be limited to the population in its licensed indication

Recognising the significantly higher ICER threshold through the HST route (£100,000/QALY, not including QALY weightings) than STA, this criterion aims to ensure that the eligible population for technologies appraised via the HST route remains small. In doing so, it seeks to support patient access to treatments for ultra-rare diseases while avoiding an impact on overall NHS expenditure such that access to new and effective treatments in wider patient groups might be affected.

During the consultation period on the refined criteria, stakeholders queried the interaction between criteria 1 and 3.[5] NICE clarified that criterion 1 assesses whether the disease of interest can indeed be considered to be ultra rare (ie using a prevalence threshold of 1100 or fewer patients in England), whereas criterion 3 focuses on the size of the treatable population for that ultra-rare disease (ie indication for the technology). NICE has set an acceptable treatment size of 300 patients, aligned with the previous criteria and reinforcing their view that the HST route should only be applied in exceptional circumstances. Again, given the paucity of robust epidemiological data available in rare diseases, stakeholders called for greater flexibility in estimating the number of treatable patients; however, NICE considered that this would contradict the objective of the refined criteria in improving the transparency and predictability of HST routing decisions and rejected this request.

A sub-requirement of criterion 3 is that the technology must be the first treatment licensed for the indication under appraisal. Stakeholders raised concerns regarding this condition.[5] However, NICE acknowledged that, while this requirement may be perceived as disadvantaging manufacturers of follow-on therapies for the same patient population, it reflects a necessary balance between facilitating access to treatments for ultra-rare diseases and mitigating the inevitable reduction in overall health gain across the NHS.

Of the nine appraisals assessed by the NICE prioritisation board using the refined HST criteria, four were considered to meet this criterion. This again illustrates that even the seemingly objective measure of prevalence can be a point of disagreement between NICE and manufacturers when considering HST eligibility. In determining disease epidemiology as part of its decision-making, NICE undertook calculations using published literature and registration data, while also placing significant focus on clinical expert opinion and input from patient organisations when estimating the eligible patient population in practice.



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#4

Criterion 4: There are no effective treatment options

Criterion 4 requires that the technology is likely to offer substantial additional benefit for people with the ultra-rare disease over existing established clinical management, and the existing established clinical management is considered to be inadequate. During consultation, stakeholders called for NICE to provide clear guidance on the types of data, evidence and expert opinion that could be used to determine what constitutes "substantial" additional benefit, "inadequate" clinical management and "no other" treatment options.[5] NICE responded that additional benefit may include improvements in patient quality of life or clinical outcomes, but noted that universally applicable guidance is not feasible given the significant heterogeneity in clinical presentation and symptom burden across ultra-rare diseases. Although not explicitly addressed by NICE during consultation, "inadequate" clinical management has previously been interpreted as situations when available therapies address only disease symptoms rather than the underlying pathophysiology.

Stakeholders also expressed concern regarding the inclusion of off-label treatments as part of standard care in HST routing assessments.[5] They argued that this approach could disincentivise manufacturers from launching products for rare diseases in the UK, potentially limiting patient access to innovative, licensed therapies. NICE, however, maintained that there is insufficient justification to exclude off-label treatments from consideration as established clinical management, noting that this is consistent with approaches taken in standard STAs, when off-label treatments may be included as comparators.

Of the four criteria, this was the least frequently met, being satisfied in only one of the nine appraisals considered for HST routing since April 2025. In that case, NICE primarily relied on published evidence (including conference abstracts and posters) to support its assessment of substantial additional benefit, alongside input from key stakeholders regarding the inadequacy of existing management.

In the eight appraisals in which criterion 4 was not met, the NICE prioritisation board cited a range of reasons, including that the condition itself did not require direct clinical intervention (with treatment instead focused on managing symptoms), the availability of adequate existing treatment options (three appraisals concerned ultra-rare diseases for which NICE-recommended technologies were already available) and a lack of substantial additional benefit in terms of improvements in survival or quality of life. Notably, in ID6388, NICE stated that an 8.9-month improvement in median overall survival, against a baseline median overall survival of 6–7 months, was not considered to be sufficient to qualify as a "substantial benefit", suggesting that NICE is looking for truly transformative health benefits when applying this criterion.



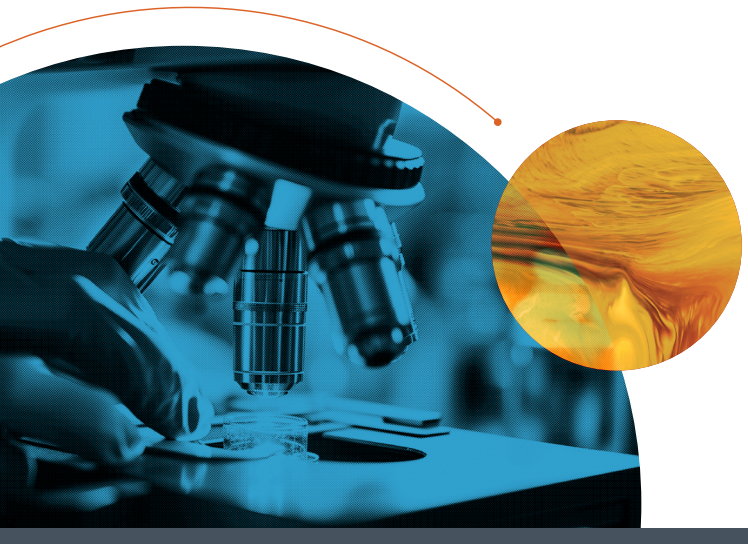
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IS THE HST ROUTE BECOMING LESS ATTAINABLE?

In line with the requirement for NICE to maintain cost neutrality, its impact assessment of the April 2025 refinements to the HST criteria concluded that the number of technologies routed to HST would not be expected to change compared with the previous checklist.[2] As part of this assessment, NICE conducted a retrospective analysis of routing decisions under the 2022–2025 criteria, identifying only two discordant outcomes between the existing and proposed frameworks (one in each direction).

However, the predictability of the revised criteria remains uncertain and appears less clear-cut than intended. Research presented at ISPOR Europe 2025, including posters from multiple health economics and outcomes research organisations, suggests a variation in how stakeholders interpret the routing criteria and determine HST eligibility.[6–8] Notably, two analyses indicated that fewer technologies would be routed to HST under the revised criteria, which is consistent with expectations for a refinement aimed at tightening definitions and reducing subjectivity.[8,9]

Although some degree of ambiguity is inevitable in any criteria designed to apply across diseases with heterogeneous clinical presentations, a clear misalignment remains between NICE and manufacturers in how key concepts such as “substantial negative impact” and “substantial additional benefit” are interpreted.



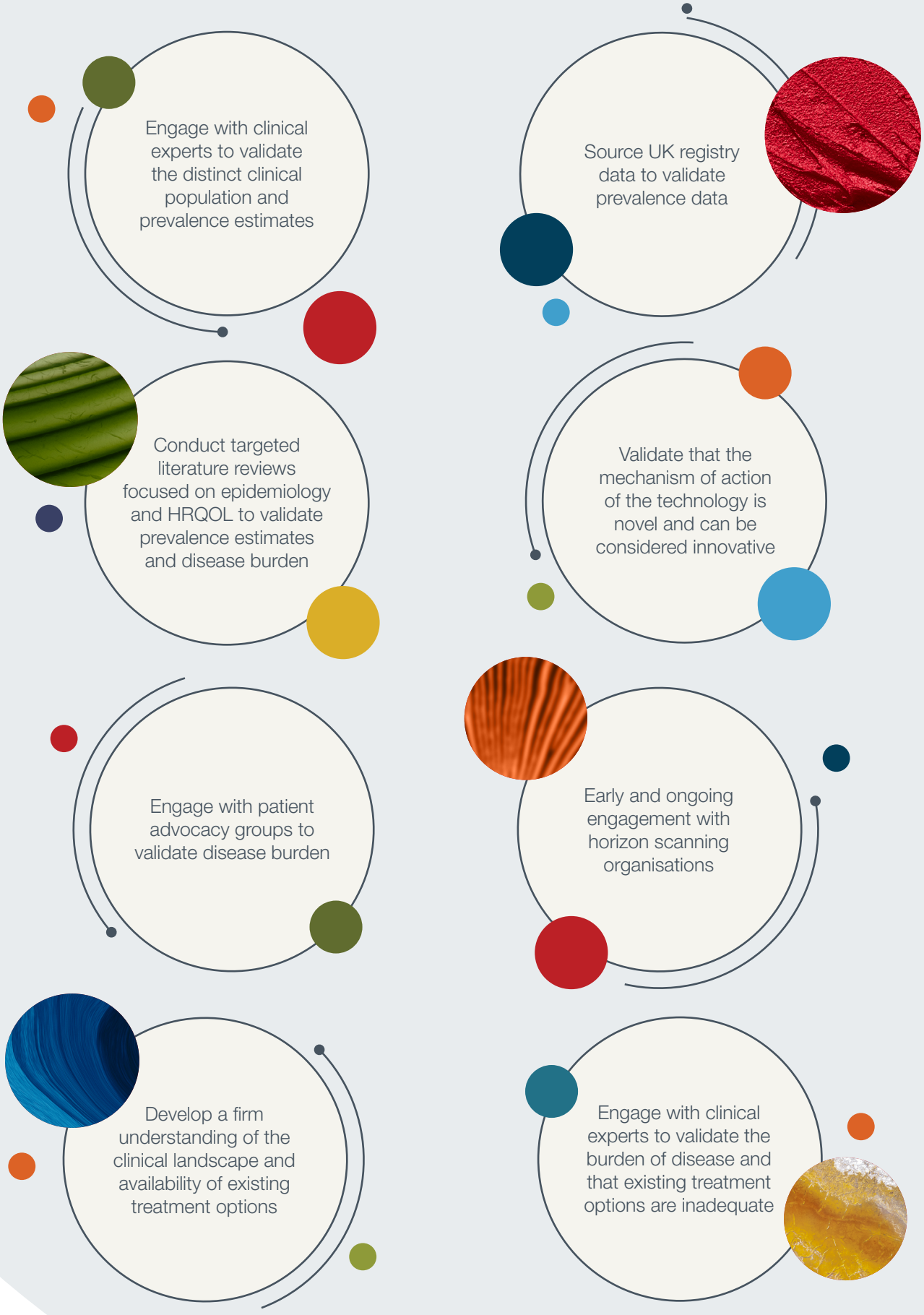
ADVICE TO MANUFACTURERS

With the HST route possibly becoming less attainable with the refined criteria, companies will be naturally considering how they can put their best foot forward and limit uncertainties ahead of NICE considering their technology for routing via the HST criteria.

Following our review of published HST checklists using the refined criteria, we have identified and recommend the following key activities to support and limit uncertainties during HST routing decisions in Figure 4.

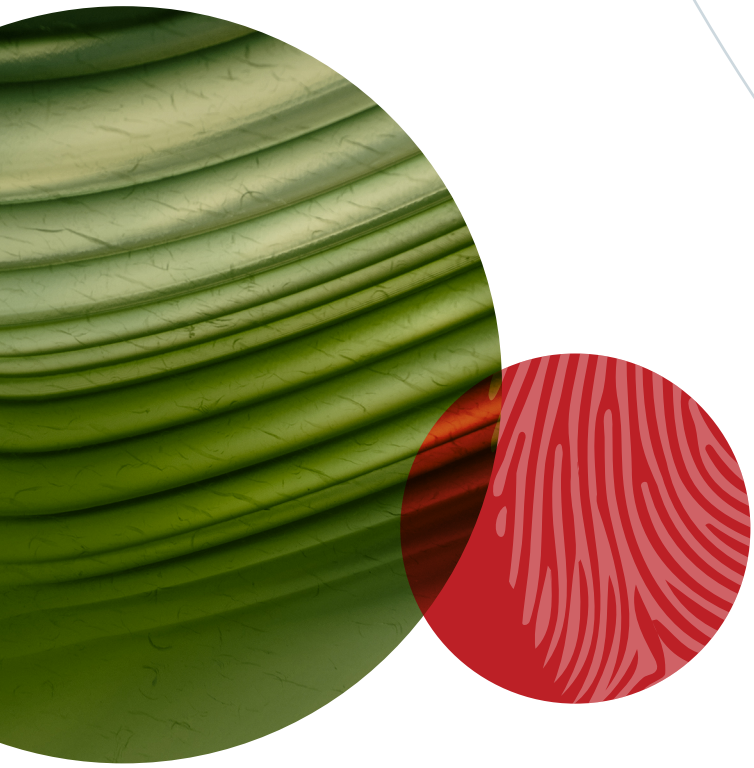
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Figure 4. Key activities to support and limit uncertainties during HST routing decisions



HRQOL, health-related quality of life; HST, highly specialised technology; NICE, National Institute of Health and Care Excellence

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Companies still retain the right to appeal the routing decision of NICE when there is disagreement; however, as noted in our previous HST white paper, changes to routing outcomes are exceedingly rare and are likely to become even less frequent under the refined criteria.[3] This was illustrated at the NICE May 2026 public board meeting when a NICE representative outlined that a group of charities and special interest groups requested that the prioritisation board change their HST routing decision for tovorafenib as a treatment option for low grade glioma [ID6557].[10] The groups argued that existing treatment options are inadequate and that the only comparably effective alternative is accessible to only a minority of the patient population. Nevertheless, the NICE guidance executive upheld the original decision, citing insufficient high-quality efficacy evidence for tovorafenib relative to other treatment options and concluding that the eligible population is too large to meet the threshold for HST consideration.

Although greater consistency in HST routing criteria offers sponsors clearer guidance at the outset, it also raises the stakes for early eligibility assessment. Companies developing therapies for conditions at the boundary of rare and ultra-rare disease will need to invest in robust comparative evidence and realistic population estimates well ahead of any NICE engagement – not as preparation for appraisal, but as a prerequisite for securing the right routing outcome from the start.

If you would like advice on your suitability for the HST programme, or support with an upcoming orphan medicine, please contact mark.orchard@cogentia.co.uk and david.aitken@cogentia.co.uk to learn more about how Cogentia can support your UK health technology assessment needs.

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