

# FOUR IS THE NEW SEVEN: THE APPLICATION OF NEW ROUTING CRITERIA FOR NICE'S HST PROGRAMME

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## BACKGROUND

- NICE updated the scoping criteria for the highly specialised technology (HST) programme in 2022 following consultation with stakeholders.
- The seven previous criteria<sup>1</sup> were streamlined to four<sup>2</sup> (**Figure 1**), with the aim to make the “routing decision clearer, consistent, more transparent and precise to provide greater clarity, precision and predictability for the routing of topics”.

## OBJECTIVE(S)

- This study analysed products that were accepted to HST previously<sup>3</sup> against the 2022 criteria to test the hypothesis that the new criteria enable greater predictability for the routing of topics, as per the NICE rationale for changes.

## METHODS

- Nineteen drugs assessed via HST (20 appraisals) were assessed against the previous and new criteria to assess whether NICE would have made a different decision about routing the product to HST under the new criteria.
- Two approaches were used; one applying a stringent interpretation of criteria and one applying a less stringent interpretation, to account for a range of subjective interpretation in the application of each of the criteria.

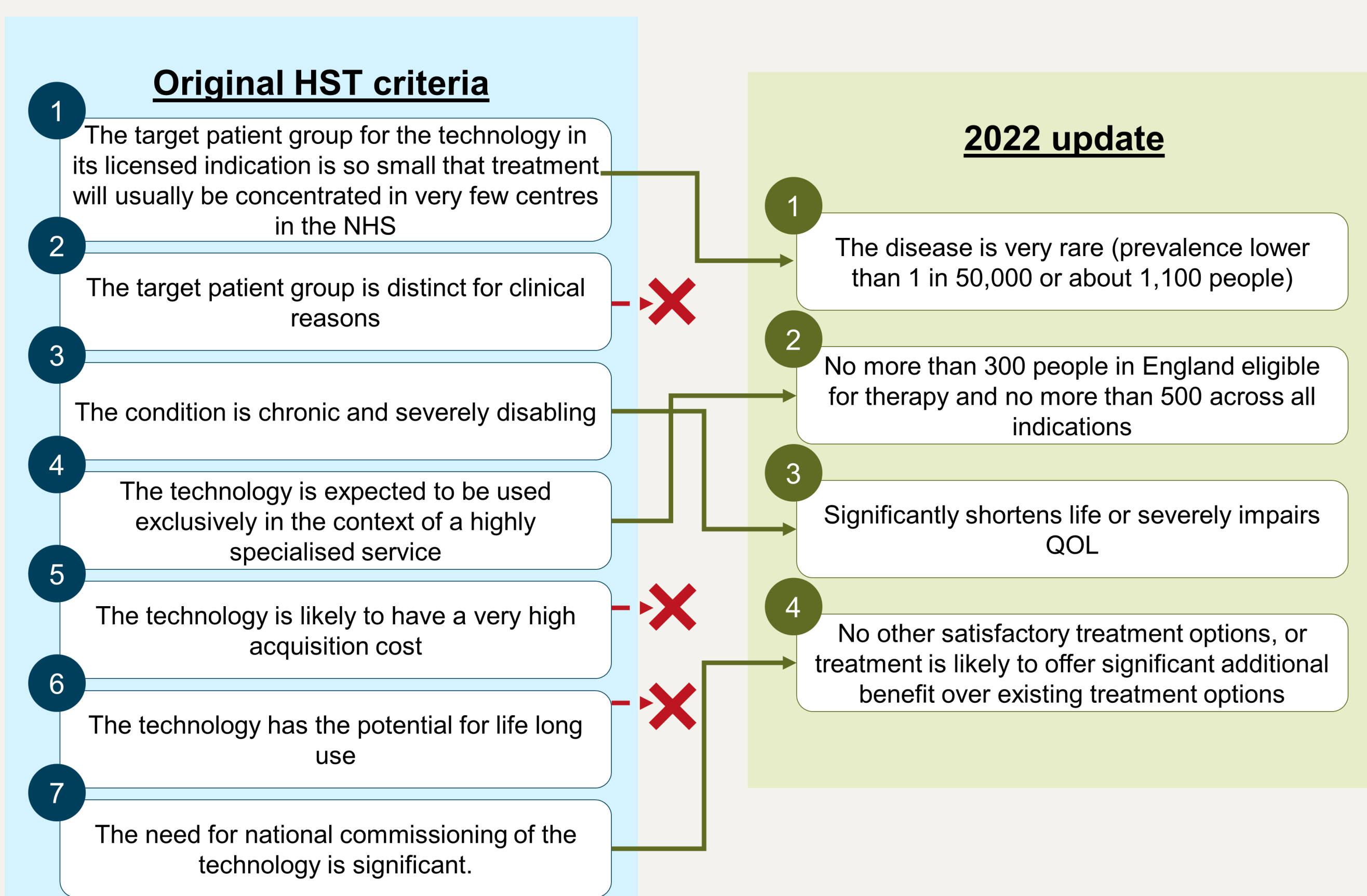


\*where possible, data was sourced from NICE documents e.g.. committee papers and supplemented where required

## RESULTS

- **Figure 1** depicts the relationship between the seven original criteria and the four updated criteria.<sup>1,2</sup>
- Themes covered by criteria 2, 5 and 6 from the original seven criteria do not appear to be reflected in the 2022 update

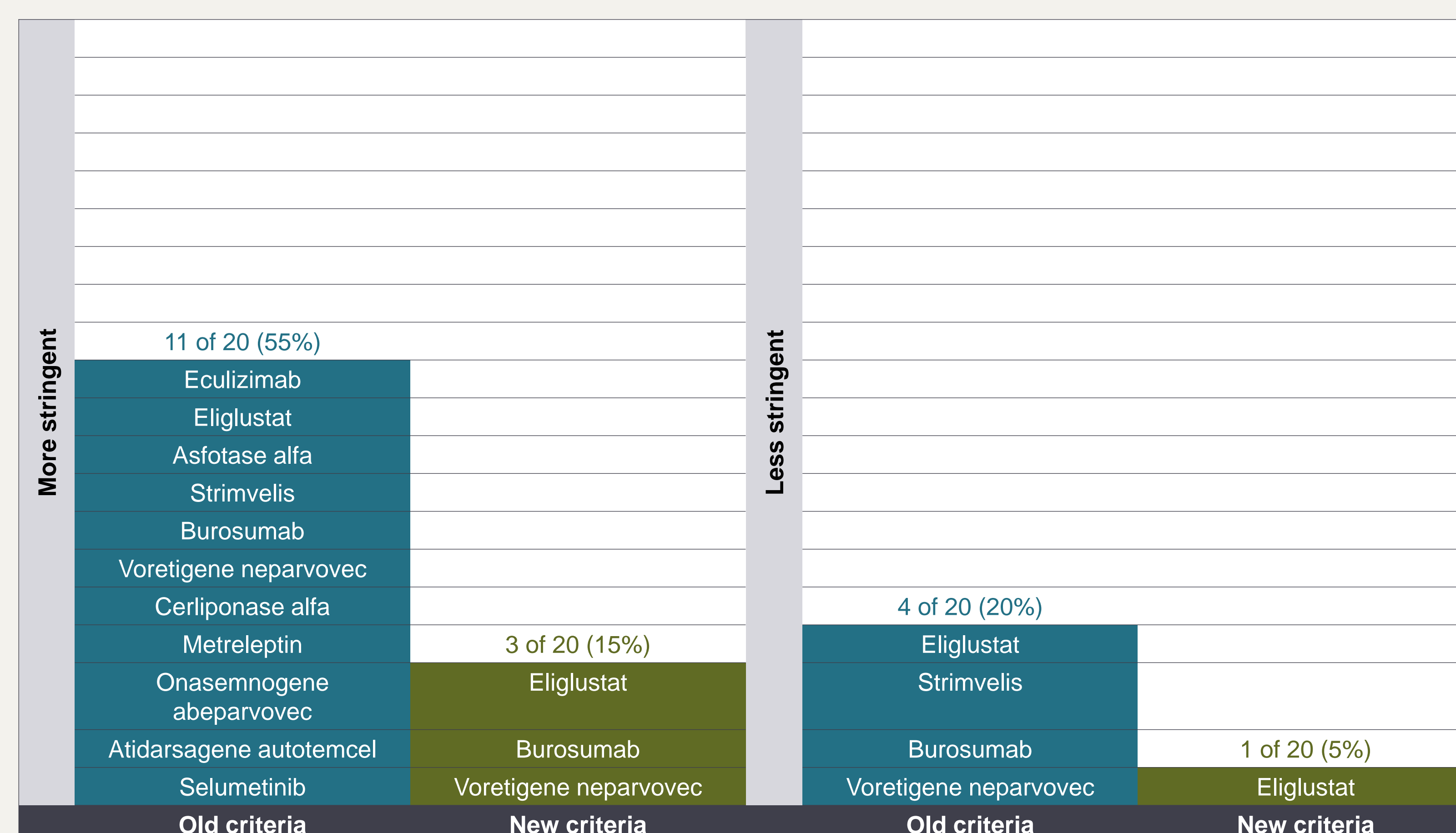
**Figure 1** Comparison of original HST criteria and 2022 update to criteria



- When applying each set of criteria stringently, only 9 of 20 (45%) appraisals met all old criteria, vs 17 of 20 (85%) meeting new criteria.
- When applied less stringently, this changes to 16 of 20 (80%) meeting old criteria, vs 19 of 20 (95%) meeting new criteria.

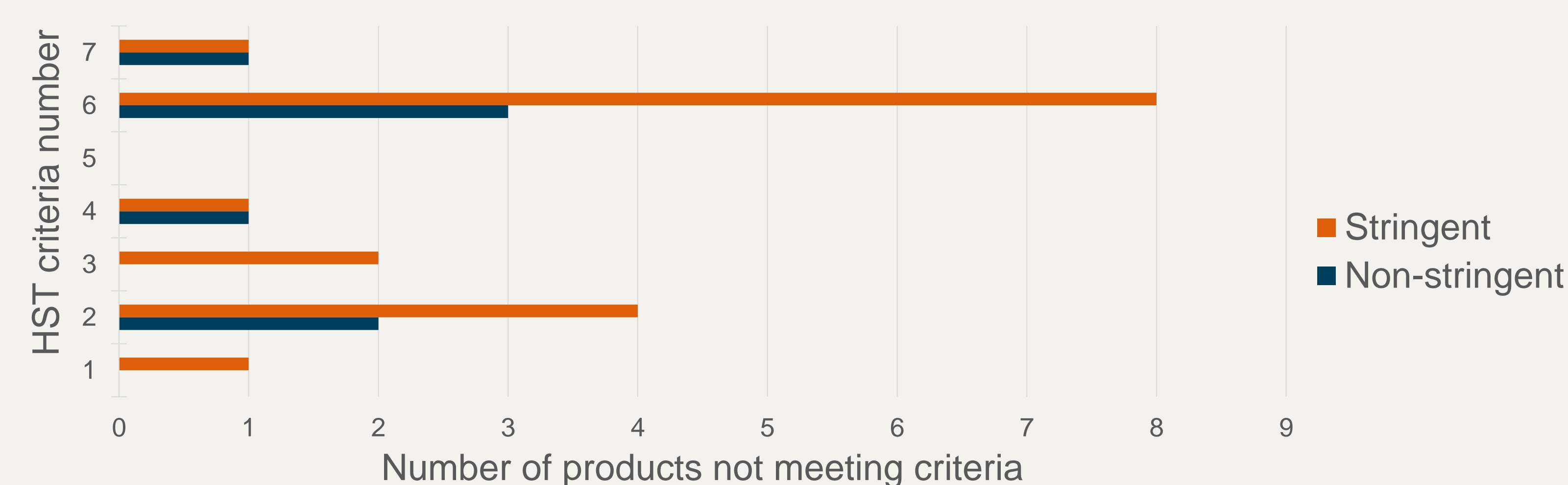
- Eliglustat<sup>4</sup> failed to meet at least one criteria in all assessments. (**Table 1**)
- Criteria 7 (original HST) and 4 (2022 update), which both relate to the need for commissioning and availability of current treatment options, were not deemed to have been met by eliglustat as Type 1 Gaucher disease is considered treatable and mild, and the use of Enzyme replacement therapy (ERT) has proven effective.<sup>4</sup>

**Table 1** Products routed via HST not meeting the original and 2022 HST criteria according to the stringency of interpretation applied



- Of the original HST criteria:
  - the most commonly failed was criteria 6: “The technology has the potential for life long use”;
  - Criteria 2, “the target patient group is distinct for clinical reasons”, was the next most failed;
  - Criteria 5, “the technology is likely to have a very high acquisition cost”, was met by all products.

**Figure 2** Number of routed HST products not meeting original HST criteria, by criteria



## DISCUSSION

- The 2022 update to the HST criteria appears to improve the confidence with which HST routing decisions are able to be anticipated by interpretation of the criteria.
- The criteria with themes that were removed in the 2022 update (criteria 2, 5 and 6) corresponded with criteria that:
  - 1. were not commonly met even by products routed to HST (criteria 2 and 6)
  - 2. was met by all products (criteria 5)
- This suggests that the changes constitute a reasonable approach

## CONCLUSIONS

- The new HST routing criteria reflect routing decisions from NICE more consistently than the old criteria.
- The removal of criteria 2, 5 and 6 will reduce uncertainty and allow greater predictability in routing decisions.

## REFERENCES

- <https://www.nice.org.uk/process/pmg37/chapter/highly-specialised-technologies#the-highly-specialised-technologies-programme>
- <https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-highly-specialised-technologies-guidance/HST-interim-methods-process-guide-may-17.pdf>
- <https://www.nice.org.uk/guidance>
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