

Integrated topic prioritisation consultation: correction

We have identified a section within the live consultation document that requires removal. The impacted area is in Appendix 3 in relation to Highly Specialised Technologies. We are unable to do this during live comment collection, therefore please take this as notification of the correct wording.

If you are due to submit comments on this section, then please do so based on this revision. For anyone who has already submitted comments on this section (and therefore is unable to amend them), please send any revised comments directly to ClinicalDirectorateOffice@nice.org.uk.

Section requiring removal in consultation document (only the highlighted section):

Appendix 3 – Highly Specialised Technologies:

Normally no more than 300 people in England are eligible for the technology in its licensed indication and no more than 500 across all its indications

The smaller the number of people eligible for the technology, the more likely this criterion will be met. A technology is unlikely to be considered suitable for the highly specialised technologies programme if more than about 300 people are eligible for it.

If more than 300 people are eligible, the severity of the disease, and whether there is lack of other effective treatments or a potential for significant benefits with the proposed technology are all considered. **One-off treatments would normally be considered acceptable if they have an eligible prevalent population of up to about 50 people and an eligible incident population of no more than about 40 people a**

year. This is for the first indication under consideration for routing. This is capped at a maximum of 500 people for a technology with multiple indications; this means all new active substances in their first indication and extensions to their marketing authorisation to add a significant new therapeutic indication, consistent with the definitions in the [2024 Department of Health and Social Care voluntary scheme for branded medicines, pricing, access and growth](#).

NICE has the discretion to apply some flexibility in these cases based on information and evidence gathered by the scoping exercise.

Correct statement (removing the highlighted section from the current consultation):

Appendix 3 – Highly Specialised Technologies:

Normally no more than 300 people in England are eligible for the technology in its licensed indication and no more than 500 across all its indications

The smaller the number of people eligible for the technology, the more likely this criterion will be met. A technology is unlikely to be considered suitable for the highly specialised technologies programme if more than about 300 people are eligible for it. If more than 300 people are eligible, the severity of the disease, unavailability of other effective treatments or a potential for significant benefits with the proposed technology are all considered. This is for the first indication under consideration for routing and it is capped at a maximum of 500 people for a technology with multiple indications. This includes all new active substances in their first indication and extensions to their marketing authorisation to add a significant new therapeutic indication, consistent with the definitions in the [2024 Department of Health and Social Care voluntary scheme for branded medicines, pricing, access and growth](#).

NICE has the discretion to apply some flexibility in these cases based on information and evidence gathered by the scoping exercise.