# Highly Specialised Technologies (HST) criteria checklist

# Vorasidenib for treating astrocytoma or oligodendroglioma with IDH1 or IDH2 mutations after surgery in people 12 years and over [ID6407]

**Introduction**

The NICE HST criteria checklist is to highlight where a technology meets/partially meets or does not meet the criteria for routing to the HST programme. Its purpose is to show the details of why a technology may not be appropriate for HST evaluation, but also where it has been identified as suitable. For more information, please see section 7 of NICE health technology evaluation topic selection: the manual.

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| Met | There is clear and strong evidence that the criterion is met |
| Not met | There is some, but not enough clear evidence that the criterion is met or<br>There is no evidence or limited evidence that the criterion is met. |

**Anticipated MA wording:** [redacted]

| Number | Criterion | Description of how the technology meets the criteria | Does the technology meet the criteria? |
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| 1. | The disease is very rare defined by 1:50,000 in England | This criterion considers the condition, not the indication specific population.<br><br>Astrocytomas develop from glial cells called astrocytes, and can be grade 2, 3 or 4. Oligodendrogliomas develop from glial cells called oligodendrocytes, and can be grade 2 or 3[1]. According to 1 study[2], for astrocytoma and oligodendroglioma, the age-standardised incidence rate in adults in England in 2017 was:<br><br>• Astrocytoma: around 1.25 per 100,000 in males and around 1 per 100,000 in females<br>• Oligodendroglioma: around 0.55 per 100,000 in males and around 0.45 per 100,000 in females<br><br>The Prioritisation Board (PB) considered that these forms of glioma are clinically distinct from | Met |

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| | | another form of glioma, glioblastoma, which is grade 4. The treatment under consideration can only be effective in astrocytoma and oligodendroglioma. In addition, prognosis differs between these forms of glioma, with glioblastoma being associated with significantly lower survival rate.<br><br>Therefore, this criterion is met. | |
| 2. | 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 | • Study by Wanis et al. (2021)[2] reports on cases of primary brain tumour diagnosed in England between 1995 and 2017.<br>• Study included ICD-10 codes C70, C71, D32, D33, D42 and D43.<br>• Selecting these codes on CancerData (NHS Digital) shows an average of 9076 diagnoses per year for 2016-2020.<br>• Wanis study states that 9.36% of cases were astrocytoma, 3.27% were oligodendroglioma.<br>• This equates to (0.0936*9076)+(0.0327*9076)=1146 cases of newly diagnosed astrocytoma and oligodendroglioma per year on average in England.<br>• It is unclear how many of these would have surgery. One clinician suggests around 60% of patients with low-grade glioma would have surgery within a year of diagnosis.[3] This would mean potentially **680** patients. NHS England clinical input suggested a higher proportion may have surgery.<br>• Around 80% of cases would have IDH mutation: 544 cases diagnosed each year.<br>• These figures are only for adults, so the population eligible for vorasidenib (ages 12 and over) could be higher.<br>• Company estimates that 33% are grade 2[4] – the NICE technical team notes that this figure is from a study in India of patients having surgery at 1 hospital. It relates to all gliomas, therefore, 33% of 544 is not the relevant calculation. It is also unclear how representative this single centre international study would be of the population in England. | Not met |

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| | | • Company estimates 35-51% are not in immediate need of chemo/radiotherapy. The NICE technical team notes that 35% comes from a study referring to watch and wait before surgery[5]. The NICE technical team notes that 51% comes from a study referring to a survey of centres[6], so it refers to a percentage of centres.<br>• The company estimated that 79 people per year would be eligible for vorasidenib<br>• The NICE technical team notes that this is the incident population and the prevalent population would be expected to be significantly higher.<br><br>NICE technical team estimate of prevalent population in England (total population 57,690,300[7]):<br>○ Astrocytoma: Incidence is 1.12 per 100,000[2]. Median survival is ~ 7 years[8]. Estimated prevalence (1.12*7)*(57,690,300/100,000) = 4,523<br>○ Oligodendroglioma: Incidence is 0.5 per 100,000[2]. Median survival is >5 years[9]. Estimated prevalence (0.5*5)*(57,690,300/100,000) = 1,442<br>○ This is likely an overestimation because it is unlikely someone would be eligible for vorasidenib for their lifetime.<br>○ These figures are not for IDH-mutated disease, which may have improved survival compared with non-IDH-mutant disease[10].<br>○ The above calculation does not account for [redacted] or age (over 12 years).<br>• Clinical input obtained by NHS England suggested that it is very likely that over 600 people would be eligible for vorasidenib in the prevalent population. | |

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| | | Based on the above calculations and clinical input, whilst acknowledging the likely overestimation in the NICE technical team figures, it is very likely that the number eligible for the technology would be over 300 and therefore this criterion is not met. | |
| 3. | The very rare disease for which the technology is indicated significantly shortens life or severely impairs quality of life | • Grade 2 tumours, also called low-grade gliomas, are defined as being infiltrative gliomas — the tumour cells penetrate into the surrounding normal brain, making surgical cure more difficult. Most patients with grade II glioma (oligodendrogliomas, astrocytomas, mixed oligoastrocytomas) are young people who often present with seizures. People with oligodendrogliomas have a better prognosis than people with an astrocytoma.[11]<br>• For all malignant neoplasms of the brain, 1-year survival is 41.7% and 5-year survival is 12.9%.[12]<br>• Around 90% of children with grade 1 or 2 astrocytoma survival for 5 years or more after surgery. For adults with astrocytoma, the average survival time after surgery is 6-8 years.[8]<br>• Around 66-78% of people with a grade 2 oligodendroglioma survive for 5 years or more after diagnosis.[9] | Met |
| 4. | There are no other satisfactory treatment options, or the technology is likely to offer significant additional benefit over existing treatment options. | There are other existing treatment options for glioma:<br>• NICE NG99 recommends initial surgery, followed by radiotherapy and up to 6 cycles of PCV chemotherapy for some people.<br>• NICE TA121 recommends temozolomide as an option for treating newly-diagnosed glioblastoma multiforme in patients with a World Health Organization performance status of 0 or 1, and carmustine implants for treating newly diagnosed high-grade glioma only for patients in whom 90% or more of the tumour has been resected.<br>• NICE TA977 recommends dabrafenib with trametinib for treating BRAF V600E mutation-positive glioma in children and | Met |

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| | | young people aged 1 year and over who need systemic treatment.<br><br>There is some evidence that vorasidenib could offer additional benefit over existing treatment options:<br><br>• Vorasidenib is a first-in-class dual mutant IDH1/2 inhibitor with brain penetration.[13]<br>• In the phase 3 clinical trial, progression-free survival was 27.7 months in the vorasidenib group and 11.1 months in the placebo group (hazard ratio for disease progression or death 0.39, 95% CI 0.27 to 0.56).[13] | |

**References**


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