# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

# Final draft guidance

# Durvalumab with tremelimumab for untreated advanced or unresectable hepatocellular carcinoma

# 1 Recommendation

1.1 Durvalumab plus tremelimumab can be used, within its marketing authorisation, as an option for untreated advanced or unresectable hepatocellular carcinoma (HCC) in adults. Durvalumab plus tremelimumab can only be used if the company provides it according to the commercial arrangement (see section 2).

# What this means in practice

Durvalumab plus tremelimumab must be funded in the NHS in England for untreated advanced or unresectable HCC in adults, if it is considered the most suitable treatment option. Durvalumab plus tremelimumab must be funded in England within 90 days of final publication of this guidance.

There is enough evidence to show that durvalumab plus tremelimumab provides benefits and value for money, so it can be used routinely across the NHS in this population.

# Why the committee made this recommendation

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Usual treatment for untreated advanced or unresectable HCC includes atezolizumab plus bevacizumab, or lenvatinib or sorafenib alone. Most people have atezolizumab plus bevacizumab.

Evidence from a clinical trial suggests that durvalumab plus tremelimumab increases how long people live compared with sorafenib. Indirect comparisons suggest that durvalumab plus tremelimumab is likely to work as well as atezolizumab plus bevacizumab, and that is likely to increase how long people live compared with lenvatinib.

The most likely cost-effectiveness estimates are within the range that NICE normally considers an acceptable use of NHS resources compared with some of the usual treatments. So, durvalumab plus tremelimumab can be used.

# 2 Information about durvalumab plus tremelimumab

# Marketing authorisation indication

2.1 Durvalumab (Imfinzi, AstraZeneca) plus tremelimumab (Imjudo, AstraZeneca) is indicated 'for the first line treatment of adults with advanced or unresectable hepatocellular carcinoma (HCC)'.

# Dosage in the marketing authorisation

2.2 The dosage schedule is available in the <u>summary of product</u> characteristics for durvalumab.

# **Price**

- 2.3 The list price of durvalumab is £592.00 per 2.4-ml vial and £2,466.00 per 10-ml vial (excluding VAT; BNF online, accessed April 2025). The list price of tremelimumab is £20,610.00 per 15-ml vial (excluding VAT; BNF online, accessed April 2025).
- 2.4 The company has a commercial arrangement for durvalumab (a commercial access agreement) and for tremelimumab (a simple discount

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patient access scheme). These make durvalumab plus tremelimumab available to the NHS with a discount. The size of the discount is commercial in confidence.

# 3 Committee discussion

The <u>evaluation committee</u> considered evidence submitted by AstraZeneca, a review of this submission by the external assessment group (EAG), and responses from stakeholders. See the <u>committee papers</u> for full details of the evidence.

# The condition

# **Details of condition**

3.1 Hepatocellular carcinoma (HCC) is the most common form of liver cancer in England, accounting for 65% of primary liver cancer diagnoses in men and 34% of diagnoses in women in 2021. It is commonly associated with liver cirrhosis (scarring of the liver), which can be caused by viral infections such as hepatitis B or C, excessive alcohol intake or other conditions that result in chronic inflammation of the liver. NHS Cancer Registration Statistics show there were 3,021 new HCC diagnoses in England in 2021. Symptoms of HCC include abdominal pain and swelling, loss of appetite, fatigue and jaundice. In advanced HCC, people may also experience confusion or disorientation caused by hepatic encephalopathy. The patient expert said these symptoms are distressing, debilitating and have a substantial impact on quality of life. They can make it difficult for people to eat, breathe and function normally. The prognosis for HCC is poor, with only 38% of people still alive 1 year after their diagnosis. The patient expert explained that their HCC diagnosis had been devastating. The committee concluded that advanced or unresectable HCC has a severe effect on both quality and length of life.

# **Treatment pathway**

#### **Current treatment**

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3.2 The goal of treatment for advanced or unresectable HCC is to delay progression of the condition and prolong life. The treatment used depends on the location and stage of the cancer, and how well the is liver functioning. In the NHS, standard care for advanced or unresectable HCC is systemic therapy with atezolizumab plus bevacizumab, or a tyrosine kinase inhibitor (lenvatinib or sorafenib). The NHS England Cancer Drugs Fund lead confirmed that around 69% of people with HCC have first-line treatment with atezolizumab plus bevacizumab. Around 16% of people with HCC have lenvatinib and 15% have sorafenib. The clinical experts said that atezolizumab plus bevacizumab is typically preferred over lenvatinib or sorafenib because of superior efficacy. But atezolizumab plus bevacizumab is not suitable for people with contraindications such as variceal bleeding, hypertension, renal dysfunction or tumour bleeding. Lenvatinib or sorafenib are typically used when atezolizumab plus bevacizumab is not suitable. One of the clinical experts explained that some healthcare professionals may prefer lenvatinib or sorafenib because of familiarity with tyrosine kinase inhibitors. Lenvatinib is typically preferred over sorafenib because of superior clinical benefit. The patient expert said that people with HCC often feel frustrated by the limited treatment options, particularly because existing options may not be suitable for them or may have unmanageable side effects. The committee concluded that atezolizumab plus bevacizumab is the most used treatment in this population. But lenvatinib and sorafenib are still used by some people.

# **Unmet need**

3.3 During the first committee meeting, the clinical experts explained that they would likely use durvalumab plus tremelimumab when atezolizumab plus bevacizumab is not suitable. Atezolizumab plus bevacizumab would continue to be their first choice because of familiarity with the treatment and a lack of evidence to justify preferring durvalumab plus tremelimumab. But they noted that, because the 2 regimens have different

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side-effect profiles, having durvalumab plus tremelimumab available as a treatment option would enable more people to benefit from immunotherapy. Patient submissions stated people with advanced or unresectable HCC are fearful of the future because of the poor prognosis. They would value having extra time to spend with their families and to put their affairs in order. So, people with HCC would welcome any new treatments, especially those with the potential to extend life. The committee concluded that people with untreated advanced or unresectable HCC would welcome an additional treatment option, particularly when atezolizumab plus bevacizumab is not suitable.

# Clinical evidence

# **HIMALAYA** trial

3.4 The clinical trial data for durvalumab plus tremelimumab comes from HIMALAYA, a randomised open-label phase 3 trial. HIMALAYA compared STRIDE (a single dose of tremelimumab plus durvalumab taken every 4 weeks) with sorafenib. It included adults with advanced or unresectable HCC (Barcelona Clinic Liver Cancer stage B or C), who were ineligible for locoregional therapy and had not had previous systemic treatment. The EAG raised concerns about the generalisability of HIMALAYA to the NHS population. It noted that no UK sites were included in the trial. It also highlighted that the median age and proportion of HCC with non-viral aetiologies were slightly lower than those seen in a UK audit of NHS patients. But the clinical experts stated that the HIMALAYA baseline characteristics were consistent with the population having systemic therapy in the NHS. They thought that the differences between the trial and NHS populations, such as the proportion of HCC with non-viral aetiologies, would not result in clinically meaningful differences in clinical outcomes. So, the committee concluded that HIMALAYA was suitable for decision making.

#### Clinical effectiveness

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3.5 In HIMALAYA, STRIDE showed a statistically significant improvement in median overall survival (OS) compared with sorafenib (16.43 months compared with 13.77 months; hazard ratio 0.76, 95% confidence interval 0.65 to 0.89, 5-year analysis). At 4 years, survival probability was 25.2% for STRIDE compared with 15.1% for sorafenib. At the primary data cutoff, there was a numerical but not statistically significant difference in investigator-assessed progression-free survival (PFS) between STRIDE and sorafenib (12.5% compared with 4.9%). The committee raised concerns about the clinical plausibility of a statistically significant benefit in OS but not in PFS for STRIDE. The company said that having nonsignificant changes in PFS but significant improvement in OS is not unusual for immunotherapy combination treatments. The clinical experts agreed that this was clinically plausible given the mechanism of action of STRIDE. They also said that this pattern has been seen in other tumour types. The clinical experts noted that it can be difficult to detect progression of HCC through imaging, which can limit the robustness of PFS data. Because this treatment is more palliative than curative, they said the most important outcome for this population is OS rather than PFS. The committee noted that, because HIMALAYA was open label, there is potential for bias in the assessment of treatment effect. This is particularly so because only investigator-assessed PFS was collected in the trial. It also questioned whether people in the STRIDE arm may have had improved survival because of fewer deaths from other causes. The clinical experts said it was not possible to determine whether someone in this population dies from their cancer or a non-cancer cause (such as liver failure). But that there was no reason to think this would differ between treatment arms. The committee concluded that STRIDE is an effective treatment compared with sorafenib.

# **Network meta-analysis**

3.6 Because of the lack of head-to-head evidence comparing STRIDE with atezolizumab plus bevacizumab, and lenvatinib, the company did a

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network meta-analysis (NMA). The analysis included data from 3 trials (HIMALAYA, IMbrave150 and REFLECT) to compare the efficacy of atezolizumab plus bevacizumab, lenvatinib and STRIDE with sorafenib. The hazard ratios for PFS and OS favoured all 3 treatments over sorafenib, but the results were not statistically significant. The exact results are considered confidential by the company and cannot be reported here. The EAG had concerns about the company's NMA. For example, it said that the methods used for the NMA and the justification for excluding studies were unclear. So, it preferred to use a previously published NMA by Vogel et al. (2023).

The EAG noted that the company's hazard ratio for the comparison of atezolizumab plus bevacizumab with sorafenib for PFS was an outlier compared with the equivalent value in several other published NMAs. The EAG said the 'outlier' PFS result could be because the company's NMA used investigator-assessed PFS rather than blinded independent central review PFS (see section 3.5). The company said that, because only investigator-assessed PFS was collected in the latest data cut of HIMALAYA, its NMA used investigator-assessed PFS across all studies for consistency. It noted that interim data from HIMALAYA using blinded independent central review was available and was comparable to investigator-assessed PFS. During consultation on the draft guidance, the company highlighted that investigator-assessed PFS was a prespecified secondary endpoint in both the REFLECT and HIMALAYA trials. In contrast, blinded independent review PFS was a post-hoc analysis in REFLECT and an exploratory endpoint in HIMALAYA. Data for this outcome was only available from the interim analysis of HIMALAYA (people with 32 weeks of follow up). So, the company said its NMA represented the best evidence base for the indirect treatment comparison.

The EAG also noted that the NMA PFS input for atezolizumab plus bevacizumab compared with sorafenib was not taken from the most

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recent publication from IMbrave150. This added to its concerns about the robustness of the company's NMA. The company said the Vogel et al. NMA did not include the latest HIMALAYA data, so did not fully capture the long-term efficacy of STRIDE. The clinical experts noted that comparing data from different trials with different populations and follow-up periods is difficult. For example, HIMALAYA had a longer median follow up than the trials for the comparator treatments.

The committee considered the 2 different NMA approaches. The committee noted that the NMA results were a key driver of cost effectiveness in the model. It acknowledged the benefits of having a consistent approach across all treatments (that is, using investigator-assessed PFS for all comparisons). But it noted the use of different criteria for PFS assessment across the studies. Also, it thought that it was unclear how the lack of blinding in the investigator PFS assessments affected the results of each clinical trial. Because of this, the committee considered that there may have been inconsistency in the investigator-assessed results. The committee agreed that it would prefer to use blinded independent review PFS when available because it is a more objective measure with less risk of bias. So, it concluded that the results from the Vogel et al. NMA were appropriate to use in the cost-effectiveness model. But the committee agreed that the NMA was an area of uncertainty because the results were not statistically significant.

# **Economic model**

# Modelling approaches for OS and PFS

3.7 The company used a 3-state partitioned survival model (progression-free, progressed disease, and death). For STRIDE and sorafenib, the company modelled OS and PFS using individual patient-level data from HIMALAYA. It found evidence that the proportional hazards assumption was violated for STRIDE compared with sorafenib (PFS and OS), so used independently fitted parametric curves. It also found evidence of

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proportional hazards violation for lenvatinib compared with sorafenib. But applying a constant hazard ratio yielded conservative cost-effectiveness estimates when compared with STRIDE. So, this approach was used as a conservative option. For atezolizumab plus bevacizumab, and lenvatinib, the company used hazard ratios from its NMA. The EAG had concerns about the company's NMA (see section 3.6). So, it also had concerns about using these hazard ratios in the model. It highlighted the inconsistency of approach between treatments (that is, using HIMALAYA data for STRIDE and sorafenib, and hazard ratios from the NMA for lenvatinib and atezolizumab plus bevacizumab). The EAG preferred to use independently fitted parametric curves using individual patient-level data for sorafenib (PFS and OS). It preferred to use hazard ratios from the Vogel et al. (2023) NMA for all other treatments. The company said it was not appropriate to apply a constant hazard ratio when the proportional hazards assumption had been violated (that is, for STRIDE). When considering the OS curves for atezolizumab plus bevacizumab and STRIDE, the committee thought that it was clinically implausible for the STRIDE OS curve to cross the atezolizumab plus bevacizumab OS curve several years after treatment had started. The clinical experts discussed the challenges of extrapolating long-term survival based on limited data. But they noted that, because of the mechanism of action of tremelimumab, a durable treatment effect that may result in the crossing of OS curves was plausible.

During the first committee meeting, the committee requested further analyses. These included using equal hazard functions from the timepoint at which the atezolizumab plus bevacizumab and STRIDE OS curves crossed. The EAG provided the scenario analysis requested by the committee. During consultation on the draft guidance, the company said that applying equal hazard functions for STRIDE and atezolizumab plus bevacizumab from the point at which their OS curves cross was not supported by data or clinical expert opinion. It said that it was considered

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a conservative assumption. It provided an alternative analysis that applied equal OS curves for STRIDE and atezolizumab plus bevacizumab from the start of the model. The company also highlighted that its modelling approach used the latest 5-year follow-up data from HIMALAYA. The committee noted that applying an equal hazard function for STRIDE and atezolizumab plus bevacizumab from the point at which the curves crossed had a small impact on the incremental quality-adjusted life years (QALYs). The committee also noted that the EAG's OS curve for STRIDE did not appear to fit the HIMALAYA Kaplan-Meier data well. This was likely because the EAG used a constant hazard ratio for STRIDE compared with sorafenib. The committee thought that there were limitations with the company's and EAG's approaches to modelling OS and PFS. But, it concluded that the company's approach made more appropriate use of the available data. So its preferred approach was to use individual patient-level data from HIMALAYA for STRIDE PFS and OS, rather than using a hazard ratio from the NMA. But, as noted in section 3.6, it preferred to use the Vogel et al. NMA as the source of OS and PFS hazard ratios for lenvatinib and atezolizumab plus bevacizumab.

# Approach to parametric extrapolation for sorafenib OS

3.8 For the sorafenib and STRIDE OS curves, the company preferred to use spline and knot models, whereas the EAG preferred a generalised gamma model for sorafenib. During the first committee meeting, the committee noted that the difference in approach to extrapolation was not considered a key model driver. But, overall, it preferred the EAG's approach for modelling OS with sorafenib. During consultation on the draft guidance, the company said that it had followed NICE Decision Support Unit (DSU) guidance for selecting the most appropriate extrapolations. It had also received advice from 7 healthcare professionals through one-to-one interviews that the spline and knot model represented the most clinically plausible extrapolation for sorafenib. The EAG said it had also followed NICE DSU guidance. The committee was satisfied that the choice of

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parametric model for sorafenib OS had a small impact on the incremental cost-effectiveness ratio (ICER). It noted the clinical validation presented by the company. Also, the committee recalled its preference to use the company's approach for modelling OS for STRIDE (which applied a 1-knot extrapolation curve to HIMALAYA individual patient-level data). So, it concluded that it preferred a 1-knot hazard model for sorafenib OS for consistency with the extrapolation of OS for STRIDE.

# Modelling time to treatment discontinuation

Time to treatment discontinuation (TTD) data was available for STRIDE 3.9 and sorafenib from HIMALAYA. But equivalent data was not available for atezolizumab plus bevacizumab, and lenvatinib. To address this, the company assumed that PFS was equivalent to TTD for these 2 treatments. The EAG raised concerns around this approach. It noted that people with HCC often continue to have treatment after progression, so TTD is not equal to PFS in clinical practice. It also had concerns about the lack of consistency in the approach between the treatments (using TTD trial data for 2 treatments, and assumption of equivalence with PFS for the other 2 treatments). It said that this could have led to bias and weaken the robustness of the model. The clinical experts agreed that it is expected that people in this population would have treatment after progression. The committee agreed that the assumption that PFS equals TTD was flawed and not reflective of clinical practice. The committee discussed that assuming equality between PFS and TTD for atezolizumab plus bevacizumab may have underestimated the ICERs for STRIDE compared with atezolizumab plus bevacizumab. During consultation on the draft guidance, the company suggested an alternative approach. It calculated the ratio between TTD and PFS for STRIDE and applied this to the PFS for atezolizumab plus bevacizumab. It applied the same approach for lenvatinib (based on the ratio between TTD and PFS for sorafenib). Based on visual evidence of non-proportionality between the TTD and PFS curves, the company calculated and applied the ratio at

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annual timepoints. The committee agreed that this approach was consistent across treatments and used available TTD data. So, the committee concluded that it preferred the ratio approach proposed by the company for modelling TTD.

# Retreatment with tremelimumab

3.10 In HIMALAYA, 31 people in the STRIDE arm who had evidence of disease progression had retreatment with 1 additional dose of tremelimumab. The company confirmed that any benefits from the additional dose were included in the efficacy data, although the costs were not included in the economic model. But it said that this applied to only a small number of people (about 8% of the STRIDE arm). The committee was concerned that including the clinical benefit for tremelimumab retreatment without including the additional costs would bias the cost-effectiveness results for STRIDE. It asked for a scenario analysis that included the costs of the additional doses of tremelimumab in the model. During consultation on the draft guidance, the company presented this scenario analysis. But it noted that tremelimumab retreatment is not permitted within the marketing authorisation so this would not happen in clinical practice. The company also highlighted that there was unlikely to be a meaningful bias in the survival extrapolations for STRIDE because of the small proportion of people that had tremelimumab retreatment. The committee considered that including the costs of tremelimumab retreatment had a small impact on the ICER. So, it concluded that it was appropriate to not include these costs in the model.

# Other assumptions

# Time horizon

3.11 The company base case used a 40-year time horizon. The EAG preferred to use a 20-year time horizon because this was consistent with previous technology appraisals in HCC. <a href="NICE's manual on health technology">NICE's manual on health technology</a>

<u>evaluations</u> states that the time horizon should be 'long enough to reflect Final draft guidance – Durvalumab with tremelimumab for untreated advanced or unresectable hepatocellular carcinoma

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all important differences in costs or outcomes between the technologies being compared'. The committee noted that some company scenarios showed a substantial proportion of people still alive at 20 years. So, the committee concluded that a 40-year time horizon was preferrable to ensure all incremental costs and benefits were captured in the model.

# **Utility values**

3.12 The company used EQ-5D-5L collected from HIMALAYA to inform the utility values for people having STRIDE and sorafenib. It mapped the EQ-5D-5L descriptive system data to the EQ-5D-3L value set in line with the NICE reference case. The company assumed that people having lenvatinib have the same utility value as those having sorafenib. This was because the treatments are both tyrosine kinase inhibitors and have comparable side-effect profiles. Similarly, it assumed that people having atezolizumab plus bevacizumab have the same utility value as STRIDE. This was because both regimens include immune checkpoint inhibitor drugs. The company did not use different utility values for different health states. The EAG preferred to use the same utility values across all 4 treatments, but preferred utility values to decline as people approach death. So, the company's approach was treatment dependent, whereas the EAG's approach was time dependent. The committee said that there were limitations with both approaches because of limited data collection after progression or treatment discontinuation. But, on balance, it preferred the time-dependent utility values approach used by the EAG, to reflect declining utility as disease progresses.

# Severity

3.13 The committee considered the severity of the condition (the future health lost by people living with the condition and having standard care in the NHS). The committee may apply a greater weight to QALYs (a severity modifier) if technologies are indicated for conditions with a high degree of severity. The company provided absolute and proportional QALY shortfall

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estimates in line with NICE's health technology evaluations manual. The company and EAG agreed that no modifier was appropriate when doing a pairwise comparison with atezolizumab plus bevacizumab. The company said that a severity modifier of 1.2 should be applied for any comparison against sorafenib or lenvatinib, based on the QALY shortfall. The EAG said that, because of the availability of atezolizumab plus bevacizumab as an established treatment option, no modifier should be applied for any of the comparisons (including fully incremental analyses or pairwise comparisons). During consultation on the draft guidance, the EAG calculated the proportional QALY shortfall for the HCC population having first-line treatment using the market share data in <u>section 3.2</u>. Based on these calculations, the EAG said that no severity modifier should be applied for any comparisons. The committee considered that the severity of the condition depends on which treatments are available. As noted in section 3.3, some people with HCC have lenvatinib or sorafenib. So, it concluded that a severity modifier of 1.2 should be applied for the fully incremental and pairwise comparisons between STRIDE and lenvatinib or sorafenib.

# **Cost-effectiveness estimates**

# Acceptable ICER

3.14 NICE's manual on health technology evaluations notes that, above a most plausible ICER of £20,000 per QALY gained, judgements about the acceptability of a technology as an effective use of NHS resources will take into account the degree of certainty around the ICER. The committee will be more cautious about recommending a technology if it is less certain about the ICERs presented. But it will also take into account other aspects including uncaptured health benefits. The company highlighted potential uncaptured benefits of STRIDE compared with atezolizumab plus bevacizumab. For example, STRIDE provides a less burdensome treatment regimen for people with HCC than atezolizumab plus

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bevacizumab. This is because it is administered less frequently and an endoscopy is not needed to assess bleeding risk before starting treatment. This can also affect caregivers and family members. The committee noted the potential uncaptured benefits. It also noted the level of uncertainty, specifically that:

- OS and PFS were not statistically significantly longer for STRIDE, atezolizumab plus bevacizumab or lenvatinib compared with sorafenib in either the company's or the Vogel et al. (2023) NMA.
- There was uncertainty associated with the long-term benefit of STRIDE compared with atezolizumab plus bevacizumab and lenvatinib because of the varying follow-up lengths of the clinical trials.

The committee concluded that an acceptable ICER would be around £30,000 per QALY gained.

# Committee's preferred assumptions

- 3.15 The committee concluded that its preferred assumptions for the cost-effectiveness modelling were:
  - using OS and PFS data from HIMALAYA for STRIDE and sorafenib (see <u>section 3.7</u>)
  - applying spline and knot models for STRIDE and sorafenib (see section 3.8)
  - using OS and PFS hazard ratios derived from the <u>Vogel et al. (2023)</u>
     NMA for atezolizumab plus bevacizumab and lenvatinib (see <u>section 3.6</u>)
  - using TTD data from HIMALAYA for STRIDE and sorafenib, and applying ratios between TTD and PFS for STRIDE to atezolizumab plus bevacizumab, and ratios between TTD and PFS for sorafenib to lenvatinib (see section 3.9)
  - using a time-dependent approach for utility values (see section 3.12)

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- using a 40-year time horizon (see section 3.11)
- applying no severity modifier for comparisons between STRIDE and atezolizumab plus bevacizumab, but applying a modifier of 1.2 for pairwise and fully incremental comparisons between STRIDE and sorafenib or lenvatinib (see section 3.13).

The committee noted that, according to clinical expert opinion and data from NHS England, atezolizumab plus bevacizumab is used most commonly in this population. The committee acknowledged that lenvatinib and sorafenib are taken by some people, typically when atezolizumab plus bevacizumab is contraindicated or the side effects are unmanageable (see <u>sections 3.2 and 3.3</u>). So, although pairwise comparisons were considered, the committee preferred to base its decision on fully incremental analysis, including all relevant comparators. Confidential discounts were applied for the intervention, comparator and subsequent treatments to best reflect the price relevant to the NHS. The price for atezolizumab plus bevacizumab differs between NHS regions because it is negotiated by the Medicines Procurement and Supply Chain. So, the committee considered analyses based on the lowest, midpoint and the highest available prices for atezolizumab plus bevacizumab. But it preferred to use the analyses based on the midpoint price in its decision making. In the fully incremental analysis, the ICER for STRIDE was below £30,000 per QALY gained.

# Other factors

# **Equality**

3.16 The committee acknowledged that HCC disproportionally affects people from poor socioeconomic backgrounds. But it agreed that this was not something that could be addressed in its recommendation.

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# Conclusion

## Recommendation

3.17 In the fully incremental analysis, the ICER for STRIDE was below £30,000 per QALY gained. So, the committee concluded that durvalumab plus tremelimumab can be used as an option for untreated advanced or unresectable HCC in adults in the NHS.

# 4 Implementation

- 4.1 Section 7 of the National Institute for Health and Care Excellence

  (Constitution and Functions) and the Health and Social Care Information

  Centre (Functions) Regulations 2013 requires integrated care boards,

  NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 90 days of its date of publication.
- 4.2 Chapter 2 of Appraisal and funding of cancer drugs from July 2016

  (including the new Cancer Drugs Fund) A new deal for patients,

  taxpayers and industry states that for those drugs with a draft
  recommendation for routine commissioning, interim funding will be
  available (from the overall Cancer Drugs Fund budget) from the point of
  marketing authorisation, or from release of positive draft guidance,
  whichever is later. Interim funding will end 90 days after positive final
  guidance is published (or 30 days in the case of drugs with an Early
  Access to Medicines Scheme designation or cost comparison evaluation),
  at which point funding will switch to routine commissioning budgets. The
  NHS England Cancer Drugs Fund list provides up-to-date information on
  all cancer treatments recommended by NICE since 2016. This includes
  whether they have received a marketing authorisation and been launched
  in the UK.
- 4.3 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE Final draft guidance Durvalumab with tremelimumab for untreated advanced or unresectable hepatocellular carcinoma

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technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 60 days of the first publication of the final draft guidance.

4.4 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has advanced or unresectable HCC and the healthcare professional responsible for their care thinks that durvalumab plus tremelimumab is the right treatment, it should be available for use, in line with NICE's recommendations.

# 5 Evaluation committee members and NICE project team

# **Evaluation committee members**

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by committee <u>C</u>.

Committee members are asked to declare any interests in the technology being evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The <u>minutes of each evaluation committee meeting</u>, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

# Chair

# **Professor Stephen G O'Brien**

Chair, technology appraisal committee C

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# **NICE** project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

# Alice Bell, Christopher Shah and Kirsty Pitt

Technical leads

# **Alexandra Sampson**

Technical adviser

# **Kate Moore**

Project manager

# Elizabeth Bell

Principal technical adviser

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