# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Draft guidance consultation

# Serplulimab with carboplatin and etoposide for untreated extensive-stage small-cell lung cancer

The Department of Health and Social Care has asked the National Institute for Health and Care Excellence (NICE) to produce guidance on using serplulimab with carboplatin and etoposide in the NHS in England. The evaluation committee has considered the evidence submitted by the company and the views of non-company stakeholders, clinical experts and patient experts.

**This document has been prepared for consultation with the stakeholders.** It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from the stakeholders for this evaluation and the public. This document should be read along with the evidence (see the committee papers).

The evaluation committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex or sexual orientation?



Issue date: July 2025

**Note that this document is not NICE's final guidance on serplulimab with carboplatin and etoposide. The recommendations in section 1 may change after consultation.**

After consultation:

- The evaluation committee will meet again to consider the evidence, this evaluation consultation document and comments from the stakeholders.
- At that meeting, the committee will also consider comments made by people who are not stakeholders.
- After considering these comments, the committee will prepare the final draft guidance.
- Subject to any appeal by stakeholders, the final draft guidance may be used as the basis for NICE's guidance on using serplulimab with carboplatin and etoposide in the NHS in England.

For further details, see NICE's manual on health technology evaluation.

The key dates for this evaluation are:

- Closing date for comments: 20 August 2025
- Second evaluation committee meeting: 10 September 2025
- Details of the evaluation committee are given in section 4.

# 1 Recommendations

1.1 Serplulimab with carboplatin and etoposide should not be used for untreated extensive-stage small-cell lung cancer in adults.

1.2 This recommendation is not intended to affect treatment with serplulimab with carboplatin and etoposide that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS healthcare professional consider it appropriate to stop.

**What this means in practice**

Serplulimab with carboplatin and etoposide is not required to be funded in the NHS in England for untreated extensive-stage small-cell lung cancer in adults. It should not be used routinely in the NHS in England.

This is because there is not enough evidence to determine whether serplulimab with carboplatin and etoposide offers benefit and is value for money in this population.

### Why the committee made these recommendations

Usual treatment for untreated extensive-stage small-cell lung cancer is one of the following:

- platinum-based chemotherapy alone, such as carboplatin with etoposide
- atezolizumab with carboplatin and etoposide
- durvalumab with etoposide and either carboplatin or cisplatin.

Clinical trial evidence shows that serplulimab with carboplatin and etoposide increases how long people have before their condition gets worse and how long people live compared with placebo plus carboplatin and etoposide.

Serplulimab with carboplatin and etoposide has not been directly compared in a clinical trial with either of the other 2 usual treatment options (the atezolizumab or durvalumab combinations). The results of indirect comparisons with these treatment combinations are uncertain because of the methods used.

There are also uncertainties in the economic model, including:

- whether the model reflects what would happen in the NHS
- the differences in how long people are expected to stay on the different treatments
- the effects of treatment on quality of life, which are higher than would be expected for people with extensive-stage small-cell lung cancer.

Because of the uncertainties in the clinical evidence and the economic model, it is not possible to determine the most likely cost-effectiveness estimates for serplulimab with carboplatin and etoposide. So, it should not be used.

# 2 Information about serplulimab

## Marketing authorisation indication

2.1 Serplulimab (Hetronifly, Accord Healthcare) in combination with carboplatin and etoposide is indicated for 'the first-line treatment of adult patients with extensive-stage small-cell lung cancer (ES-SCLC)'.

## Dosage in the marketing authorisation

2.2 The dosage schedule is available in the summary of product characteristics for serplulimab.

## Price

2.3 The list price of serplulimab is £1,321.83 per 100-mg vial (company submission, June 2025).

2.4 The company has a commercial arrangement, which would have applied if serplulimab had been recommended.

### Carbon Reduction Plan

2.5 Information on the Carbon Reduction Plan for UK carbon emissions for Hetronifly will be included here when guidance is published.

# 3 Committee discussion

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

## The condition

### Small-cell lung cancer

3.1 Small-cell lung cancer is an aggressive type of cancer that grows rapidly and spreads quickly to other parts of the body. Common symptoms include weight loss, malaise, bone pain, breathlessness and coughing up blood. A patient expert submission explained that a diagnosis of small-cell lung cancer is devastating for the person with the disease, their families and carers because of its aggressive, symptomatic and progressive nature. Around 70% of people with small-cell lung cancer have extensive-stage disease, when the cancer has spread beyond 1 lung and the nearby lymph nodes to other parts of the body. Both patient and clinical experts highlighted that extensive-stage small-cell lung cancer (ES-SCLC) has a poor prognosis with limited treatment options. The committee recognised the severe impact that ES-SCLC has on people's quality of life and survival. It acknowledged the unmet need for more effective treatments for ES-SCLC.

### Treatment pathway and comparators

3.2 The company positioned serplulimab plus carboplatin and etoposide as a first-line treatment for ES-SCLC. Current first-line treatment options for ES-SCLC are:

- platinum-based chemotherapy, such as carboplatin with etoposide

- atezolizumab plus carboplatin with etoposide (from here, atezolizumab)
- durvalumab plus etoposide and either carboplatin or cisplatin (from here, durvalumab).

Between 10% and 20% of people with ES-SCLC move on to second-line treatment (clinical expert advice in NICE's technology appraisal guidance on atezolizumab). At the committee meeting, the clinical expert stated that first-line treatment for ES-SCLC, that is an immunotherapy plus chemotherapy, is well established in NHS practice, so no additional changes would be needed to implement serplulimab. They said that serplulimab was not expected to address the unmet need for small-cell lung cancer (see section 3.1), but it would offer an alternative immunotherapy plus chemotherapy treatment option in the first-line setting. The committee noted that the comparators atezolizumab and durvalumab were recommended in adults only if they have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 (TA638 and TA1041; see section 3.3). The NHS England national speciality adviser for cancer drugs (from here, national speciality adviser) highlighted that more than 90% of people with untreated ES-SCLC have atezolizumab. The committee concluded that serplulimab plus carboplatin and etoposide would be an alternative first-line treatment option.

## Clinical effectiveness

### Clinical trials

3.3 Clinical evidence for serplulimab plus carboplatin and etoposide came from the ASTRUM-005 trial. ASTRUM-005 was a phase 3, multicentre, randomised controlled trial comparing the effectiveness of serplulimab plus carboplatin and etoposide with placebo plus carboplatin and etoposide. The primary outcome was overall survival, which significantly improved in the serplulimab arm compared with placebo. Progression-free survival was a key secondary endpoint and significantly improved in the

serplulimab arm. The ASTRUM-005 population was people with ES-SCLC who had an ECOG performance status of 0 or 1. The committee considered whether applying a restriction to the recommended population to align with the ECOG performance status of ASTRUM-005 was appropriate. The committee noted that a similar population restriction was applied to NICE's technology evaluations for atezolizumab (TA638) and durvalumab (TA1041), in which evidence from people with an ECOG performance status of 0 or 1 was not considered generalisable to people with an ECOG performance status of 2 or higher. The clinical expert said it would be unlikely that serplulimab would be given to people with an ECOG performance status of 2 or higher. The committee thought that restricting by ECOG performance status could have implications for equality. It also noted that a restriction would not have an impact on treatment decisions as it was unlikely that serplulimab would be used by people with an ECOG performance status of 2 or higher in clinical practice. So the committee did not feel a need to restrict its recommendation by ECOG performance status.

## Generalisability of trial populations

3.4 There is no direct evidence comparing serplulimab with atezolizumab or durvalumab. Data for atezolizumab was sourced from IMpower133, a phase 3 trial comparing atezolizumab plus carboplatin and etoposide with placebo plus carboplatin and etoposide. Data for durvalumab was sourced from CASPIAN, a phase 3 trial comparing:

- durvalumab with etoposide and either carboplatin or cisplatin
- etoposide with either carboplatin or cisplatin.

All 3 trials (ASTRUM-005, Impower133, CASPIAN) used to source clinical effectiveness were similar in design. But the EAG highlighted notable differences in patient characteristics between the trials and the NHS population. All the trials had higher proportions of males, particularly ASTRUM-005 in which more than 80% of participants were male. The

EAG explained that, in the UK, lung cancer incidence is similar between males and females. Most people in ASTRUM-005 were Asian and a high proportion (19.8% of the total study population) were not smokers. Clinical advice to the EAG noted it was rare for people who do not smoke to be diagnosed with SCLC in UK clinical practice. Also, a substantial proportion of people in the trials went on to have second-line treatment, when clinical advice from TA638 suggested that between 10% and 20% of people in the NHS would have second-line treatment. Expert clinical advice to the company agreed that the subgroup analyses from ASTRUM-005 showed no difference in overall survival and progression-free survival between Asian and non-Asian subgroups. At the committee meeting, the clinical expert also suggested that there are people in the NHS with ES-SCLC who have never smoked and who tend to have a poorer prognosis than people who have smoked. So, real-world outcomes for serplulimab may be more favourable than in ASTRUM-005 in which there is a higher proportion of people who have never smoked. The EAG said ASTRUM-005 was not powered to detect significant differences based on race subgroups and there was no robust evidence to validate treatment effect modifiers in people with SCLC. The committee concluded there was uncertainty in the generalisability of the populations of ASTRUM-005, IMpower133 and CASPIAN to the NHS, so the generalisability of the trial outcomes to the NHS was unclear.

## Indirect treatment comparisons

3.5 The company presented 2 anchored matching-adjusted indirect comparisons (MAICs): one to compare serplulimab with atezolizumab and another to compare serplulimab with durvalumab. Baseline characteristics of the ASTRUM-005 intention-to-treat population were adjusted to the data from IMpower133 or CASPIAN, before applying Cox proportional hazards regressions to estimate the relative efficacy between serplulimab and either atezolizumab or durvalumab. Overall, the indirect treatment comparisons showed that serplulimab improves progression-free survival and overall survival compared with either atezolizumab or durvalumab,

with or without adjustment of baseline variables. The clinical expert noted that, in practice, they would expect similar clinical effectiveness across the immunotherapy treatments. They suggested that the improvements in progression-free survival and overall survival with serplulimab compared with the other immunotherapies were because of trial differences. The national speciality adviser also stated that they would not expect better outcomes with serplulimab. The company stated that the improved effectiveness may be because serplulimab binds to the programmed cell death protein 1 receptor (PD-1) and blocks its interaction with the ligands PD-L1 and PD-L2. It noted that both atezolizumab and durvalumab inhibit only PD-L1. The committee noted that it had not seen evidence comparing the efficacy of inhibitors that target PD-1 versus PD-L1 alone as part of the company's evidence submission and it was aware of other PD-1 inhibitors that did not show increased efficacy. The committee agreed that, if available, the company should provide evidence supporting serplulimab's stronger efficacy than other PD-1 and PD-L1 inhibitors to support the committee's decision making. The EAG highlighted that a limited number of characteristics was included in each indirect treatment comparison. The EAG noted that some characteristics, such as race and previous cancer treatment, were notably different between the trials but were not adjusted for in the base-case MAICs. The company explained that adjusting for these characteristics would result in excessively low effective sample sizes, leading to unreliable outcomes. Also, previous cancer treatment was not reported in CASPIAN. The EAG acknowledged this but noted that the uncertainty remains. At clarification, the EAG requested that the company provide a multilevel network meta-regression to address the uncertainties around between-study variations because it would allow more flexibility to generate population-adjusted outcomes. But the company asserted that the MAICs were more suitable and addressed between-trial differences through the matching and reweighting of baseline data. The EAG acknowledged that the multilevel network meta-regression would also be uncertain because of the limited population

overlap identified by the MAICs, but it maintained that this approach would have been useful to explore. The committee was concerned that the MAICs did not offer a robust approach for decision making in this appraisal. It said it was not appropriate to compare hazard ratios across 2 different matched populations. It also recalled the uncertainty in the generalisability of the trial populations to the NHS (see section 3.4) and the MAICs reflected the trial populations of IMpower133 and CASPIAN. The committee noted that the results of the unmatched Bucher indirect treatment comparisons and the MAICs were similar, implying that the treatment effect modification of the adjusted variables was not very strong. The company agreed and said it would also expect to see similar results if another adjustment method was used, such as the multilevel network meta-regression. The committee noted a multilevel network meta-regression would not address all the uncertainty around the between-study differences but would allow for comparisons to be made against the comparators in 1 population. The committee agreed that the Bucher indirect treatment comparisons were the best available evidence in the submission for comparing serplulimab with atezolizumab or durvalumab. But because these were highly uncertain, the committee requested to see a network meta-analysis (with time-varying hazard ratios; see section 3.8) that would allow for the relative effectiveness of serplulimab to both atezolizumab and durvalumab to be considered.

## Cost effectiveness

### Company's modelling approach

3.6 The company provided a partitioned survival model to estimate the cost effectiveness of serplulimab compared with atezolizumab, durvalumab and platinum-based chemotherapy alone. The model included 3 health states: progression-free, progressed disease and death. The model used a cycle length of 1 week over a 20-year lifetime horizon. The probability of being in each health state was based on extrapolated overall survival, progression-free survival and time to off-treatment (also known as time-to-

treatment discontinuation) curves. The committee concluded that, overall, the company's model structure was acceptable for decision making.

## Extrapolation of progression-free survival and overall survival

3.7 For the serplulimab and platinum-based chemotherapy-only arms, progression-free survival and overall survival were extrapolated from ASTRUM-005 trial data. The company fitted independent parametric models and selected the log-logistic as the most appropriate option for both arms and survival outcomes. The EAG noted that NICE decision support unit on survival analysis (technical support document 14) recommends testing more flexible model fits if the lines in the log-cumulative hazard plots are not straight, so a more flexible model may be more appropriate. But the EAG also acknowledged that the significant censoring of the longer-term data may mean a more flexible model is not a better fit. At clarification, the company provided additional fits using spline models with 1, 2 and 3 knots. It suggested that the 2- and 3-knot spline models for overall survival and 3-knot spline model for progression-free survival had the best fits for the data. But the 3-knot model for progression-free survival showed implausible long-term estimates because it crossed with the overall survival curves. Clinical input sought by the company said that the long-term overall survival predictions were also overestimated in the serplulimab arm. So, the company maintained its preference for the log-logistic models. The EAG preferred to apply the 3-knot spline models for both arms and survival outcomes, adjusting the longer-term survival to account for the potential overestimation of the longer-term fit. For the serplulimab arm, the EAG used a 3-knot spline model until 3.5 years followed by a 3-year treatment effect waning assumption where the hazard ratio linearly increased towards 1. The committee noted this differed from the treatment effect waning assumption applied for atezolizumab with carboplatin and etoposide in NICE's technology appraisal for atezolizumab (TA638), where treatment benefit was capped at 60 months, from which point the overall survival hazard was made equivalent to the platinum-based chemotherapy-only arm. At

the committee meeting, the EAG acknowledged that it had considered the company's log-logistic models to be clinically plausible in the long term because it adjusted its own curves to match the company's long-term survival estimates. The committee concluded that the company's log-logistic models for the serplulimab and platinum-based chemotherapy-only arms were clinically plausible and could be acceptable for decision making. But it recalled that, if recommended, serplulimab would be considered as an alternative to atezolizumab and durvalumab in practice. So, the committee would like to see:

- further comparisons of the progression-free survival and overall survival extrapolations for the serplulimab arm with the extrapolations for atezolizumab and durvalumab, and
- justification for the choice of extrapolation approach for atezolizumab and durvalumab with consideration to the expected relative treatment effect between them and serplulimab.

## Constant hazard ratios

3.8 For the comparisons with atezolizumab and durvalumab, the company applied constant hazard ratios for overall survival and progression-free survival derived from the MAICs (see section 3.5). The EAG stated that although its preferred 3-knot spline model for overall survival showed a fairly constant hazard ratio over the first 18 months, a continued constant hazard ratio may not reflect clinical reality because people having treatment would eventually experience disease progression and stop treatment. For the EAG's base case, from 3.5 to 6.5 years the hazard ratio for overall survival in the comparisons with atezolizumab and durvalumab trends towards 1. The EAG assumed that the hazard ratio for progression-free survival would be constant for the duration of the model. The EAG reported concerns with the proportional hazards assumptions between serplulimab and atezolizumab and between serplulimab and durvalumab. It suggested that sensitivity analyses using models that relax this assumption could have been done to explore the uncertainty. The

committee concluded that the validity of proportional hazards assumption between serplulimab and atezolizumab and between serplulimab and durvalumab was uncertain. It requested further analyses that model serplulimab, atezolizumab and durvalumab using a network meta-analysis with time-varying hazard ratios.

### Extrapolating time to off-treatment

3.9 Similar to overall survival and progression-free survival, the company applied independent log-logistic curves to the serplulimab and platinum-based chemotherapy-only data from ASTRUM-005 to estimate longer-term time to off-treatment. The EAG stated that the log-logistic curve for serplulimab did not fit the trial data well and may overestimate the proportion of people on treatment earlier in the model and underestimate it later in the model. The EAG preferred to apply a 3-knot spline model until 3.5 years (as with overall survival in section 3.7), then limit the proportion of people on treatment based on the percentage of people on treatment in the progression-free and progressed-disease states from the previous model cycle, applied to the number of people in those states in the current cycle. The committee noted that time to off-treatment for serplulimab maps closely to progression-free survival in ASTRUM-005. But it was aware that the ASTRUM-005 protocol allowed people to continue treatment with serplulimab after first disease progression. Similar approaches were taken in the IMpower133 and CASPIAN trials for atezolizumab and durvalumab. The committee recalled that, if recommended, serplulimab would be considered an alternative to atezolizumab and durvalumab in clinical practice. For the comparisons with atezolizumab and durvalumab, time to off-treatment was derived by multiplying the reciprocals of the hazard-ratio estimates from the MAICs for overall survival with hazard rates for the stopping treatment for serplulimab. The committee recalled its concerns with the MAICs (see section 3.5). It requested further analyses to compare time to off-treatment for serplulimab with atezolizumab and durvalumab. It requested that, where data availability allows, these include:

- a comparison of time-to-off-treatment data (such as median time-to-off-treatment values) for serplulimab, atezolizumab and durvalumab across the ASTRUM-005, IMpower133 and CASPIAN trials, respectively
- a scenario in which time to off-treatment is assumed to be equivalent to progression-free survival for serplulimab, atezolizumab and durvalumab
- a scenario in which the gap between time to off-treatment and progression-free survival for serplulimab in ASTRUM-005 is modelled to capture treatment beyond progression, and the same gap is also assumed to apply for estimating time to off-treatment for atezolizumab and durvalumab from their respective progression-free survival extrapolations
- a scenario using the trial-observed ratios of median progression-free survival to median time to off-treatment, applied to the progression-free survival curves to generate the time-on-treatment curves, per treatment arm.

## Weight and height

3.10 Dosing of serplulimab and chemotherapy treatments are based on weight and body surface area. In the model, the company used the mean body weight (68.4 kg) and height (167 cm) from ASTRUM-005. The EAG noted that the ASTRUM-005 population (predominantly Asian and male) does not reflect the NHS population (see section 3.4). It highlighted that the weight and height from the trial may not be representative of the NHS population. It highlighted a National Lung Cancer Audit, which reported that in England around 50% of people with SCLC are female and the median age at diagnosis is 70 years. It also stated that the average weight of people aged 65 to 74 is 79.3 kg and the average height is 166.8 cm (Health Survey for England). The national speciality adviser said that the median age of people having atezolizumab for untreated ES-SCLC was 68 years. The EAG suggested that using a lower weight and height than that of the NHS population could underestimate drug costs for serplulimab and platinum-based chemotherapy, for the same expected effectiveness.

This would bias results in favour of serplulimab in the comparisons with atezolizumab and durvalumab because atezolizumab and durvalumab are fixed-dose treatment regimens. It preferred to apply the height and weight from the Health Survey for England. The committee agreed that the weight and height used to inform the model should be based on the expected NHS England population.

## Health-state utility values

3.11 Utility values in the company's base case were informed by EQ-5D-5L data from ASTRUM-005, mapped to EQ-5D-3L. The values were calculated without accounting for repeated measures. The committee lead team highlighted that the company's utility values were notably higher than values derived for non-small-cell lung cancer, yet small-cell lung cancer is usually considered more aggressive. It also noted that the utility values are closer to values expected of the general population. The clinical expert agreed that the health-state utility values were higher than expected for ES-SCLC. The lead team also noted that least-squares means estimates are subject to attrition bias. The lead team suggested that a better approach would be to estimate utility values using a mixed-effects model and scenarios that explore utility values from alternative data sources. The EAG provided scenario analyses using utility values from Nafees et al. (2008) and Chouaid et al. (2013), both of which reflect a population with non-small-cell lung cancer and are not based on trial data. The committee noted that the utility values for the ASTRUM-005 non-Asian subgroup were lower than those for the overall population and closer to previously used utility values. But the committee concluded that, although the values were more clinically plausible, the small population numbers of the non-Asian subgroup added uncertainty to the results. So, the committee preferred to use the whole-population data and requested an updated analysis that uses a mixed-effects approach.

## Severity

3.12 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 (a severity modifier) to quality-adjusted life years (QALYs) if technologies are indicated for conditions with a high degree of severity. The company provided absolute and proportional QALY shortfall estimates in line with NICE's manual on health technology evaluations. Based on atezolizumab as the comparator, the company proposed a severity modifier of 1.2. The EAG provided additional analyses confirming that all comparators modelled would meet the QALY shortfall criteria for a severity modifier of 1.2. The committee noted that the absolute and proportional QALY shortfall estimates may change depending on the additional analyses requested. So, it could not yet conclude whether it was appropriate to apply a severity modifier.

## Cost-effectiveness estimates

### Acceptable incremental cost-effectiveness ratio

3.13 NICE's manual on health technology evaluations notes that, above a most plausible incremental cost-effectiveness ratio (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 committee noted the high level of uncertainty, specifically that:

- the population characteristics of the clinical trial differed from the expected NHS population and the generalisability was unclear (section 3.4)
- indirect treatment comparisons were used, including a MAIC approach that lacked robustness or an unadjusted Bucher approach (section 3.5)

- applying constant hazard ratios to the comparisons of serplulimab with atezolizumab or durvalumab may lack validity (section 3.8)
- the relative differences in time to off-treatment between serplulimab with atezolizumab and durvalumab were uncertain (section 3.9)
- the utility values sourced from ASTRUM-005 were notably higher than would be expected for people with ES-SCLC (section 3.11).

The committee also recalled that serplulimab was not expected to address the unmet need for small-cell lung cancer in the first-line setting (see section 3.2). So, the committee concluded that an acceptable ICER would be around £20,000 per QALY.

## Other factors

### Equality

3.14 The committee did not identify any equality issues.

### Uncaptured benefits

3.15 The committee considered whether there were any uncaptured benefits of serplulimab. The NICE technical team highlighted that atezolizumab could be administered subcutaneously, whereas serplulimab and durvalumab are administered only intravenously. The clinical expert noted that in their practice approximately 20% of people had switched to having atezolizumab subcutaneously in the maintenance phase of treatment. They also noted that the availability of subcutaneous administration was a factor when choosing a treatment because it has time and resource savings compared with intravenous administration. The national speciality adviser estimated that at least 50% of people were having atezolizumab subcutaneously in NHS practice. In the company's and EAG's base cases, 100% of people were assumed to have atezolizumab intravenously. The EAG provided additional scenarios exploring the cost of subcutaneous administration of atezolizumab during the maintenance phase. The clinical expert and national speciality adviser highlighted the

additional benefits of subcutaneous administration, including convenience for the patient and saved time for pharmaceutical preparation and administration. The committee noted that the unit cost of administration of atezolizumab during the maintenance phase had a small impact on the cost-effectiveness results. But it thought the additional benefits to subcutaneous administration had not been captured in the model for atezolizumab. It concluded that it would take into account any potential uncaptured benefits and disadvantages when it was presented with responses to its requests for additional analyses.

## Conclusion

### Recommendation

3.16 The committee concluded that the clinical- and cost-effectiveness evidence presented by the company was uncertain and requested additional analyses to address this uncertainty. It considered that there were no plausible cost-effectiveness estimates, so concluded that serplulimab should not be used for untreated ES-SCLC.

### The committee's additional requests

3.17 The committee could not select a preferred ICER because of the uncertainties in the evidence. The committee agreed that it would like to see the following:

- a network meta-analysis, with time-varying hazard ratios, to further explore the relative effectiveness of serplulimab to atezolizumab and durvalumab (see section 3.5 and section 3.8)
- comparisons for the extrapolation of progression-free survival and overall survival for serplulimab compared with atezolizumab and durvalumab, including justification for the selected extrapolation approach applied to the base case (section 3.7)
- further analyses comparing time to off-treatment for serplulimab with atezolizumab and durvalumab (section 3.9)

- weight and height in the model to represent the NHS population (section 3.10)
- updated health-state utility values calculated using a linear mixed-effects approach (section 3.11).

# 4 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 D.

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

## Chair

**Raju Reddy**

Vice-chair, technology appraisal committee D

## 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.

**Lauren Elston**

Technical lead

**Rachel Williams**

Technical adviser

**Kate Moore and Louise Jafferally**

Project manager

**Lorna Dunning**

Associate director

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