NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final draft guidance

Cemiplimab for treating recurrent or metastatic cervical cancer that has progressed on or after platinum-based chemotherapy

1 Recommendations

1.1 Cemiplimab can be used as an option to treat recurrent or metastatic cervical cancer that has progressed on or after platinum-based chemotherapy in adults if:

- they have not had immunotherapy
- treatment is stopped after 16 cycles (each lasting 6 weeks), or earlier if the cancer progresses or there is unacceptable toxicity, and
- the company provides cemiplimab according to the commercial arrangement (see section 2).

1.2 This recommendation is not intended to affect treatment with cemiplimab 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

Cemiplimab must be funded in the NHS in England for the condition and population in the recommendations, if it is considered the most suitable treatment

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option. Cemiplimab must be funded in England within 90 days of final publication of this guidance.

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

Why the committee made these recommendations

Usual treatment for recurrent or metastatic cervical cancer that has progressed on or after platinum-based chemotherapy (with or without immunotherapy) is single-agent chemotherapy.

Cemiplimab is licensed for people who have had platinum-based chemotherapy. This includes people who also had immunotherapy. But, for this evaluation, the company asked for cemiplimab to be considered only for people who have not had immunotherapy.

Clinical trial evidence shows that cemiplimab increases how long people have before their cancer gets worse, and how long they live, compared with single-agent chemotherapy. In this trial, people could have cemiplimab for up to 16 cycles (each lasting 6 weeks).

When considering the condition's severity, and its effect on quality and length of life, the most likely cost-effectiveness estimates are within the range that NICE considers an acceptable use of NHS resources. So, cemiplimab can be used.

2 Information about cemiplimab

Marketing authorisation indication

2.1 Cemiplimab (Libtayo, Regeneron) is indicated for 'the treatment of adult patients with recurrent or metastatic cervical cancer and disease progression on or after platinum-based chemotherapy'.

Dosage in the marketing authorisation

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

Price

2.3 The list price for cemiplimab is £4,650 per 350-mg vial (excluding VAT, BNF online accessed June 2026).

2.4 The company has a commercial arrangement (simple discount patient access scheme). This makes cemiplimab available to the NHS with a discount. The size of the discount is commercial in confidence.

Sustainability

2.5 For information, the Carbon Reduction Plan for UK carbon emissions is published on the Regeneron webpage on transparency and policies.

3 Committee discussion

The evaluation committee considered evidence submitted by Regeneron, 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

Details of condition

3.1 Cervical cancer develops when abnormal cells in the lining of the cervix grow in an uncontrolled way and form a tumour. Human papillomavirus is

detected in 99.7% of people with cervical cancer. The cancer is defined as recurrent when it has returned after treatment, and metastatic when it has spread beyond the cervix to other places in the body. Patient expert input at the committee meeting, and for NICE's evaluation of tisotumab vedotin, explained that cervical cancer substantially disrupts quality of life. They explained that living with the condition is physically and emotionally exhausting. They also highlighted that side effects from chemotherapy, such as fatigue and nausea, further affect quality of life and make it more difficult to care for young children. For people whose cancer progresses after first-line systemic treatment, there are limited treatment options available. The main aims of treatment are to relieve symptoms and improve quality of life, and to extend life. They explained that the fear of recurrence and uncertainty about the future can feel overwhelming. At the committee meeting, the patient expert also described how difficult it was to manage caring responsibilities with regular hospital visits for chemotherapy. They added that reducing symptoms, side effects of chemotherapy and the frequency of hospital visits would benefit people with the condition. They added that improvements in quality of life and increased hope provided by the potential survival benefits of cemiplimab are important considerations. The committee noted that there is a high disease burden for people with recurrent or metastatic cervical cancer that has progressed on or after platinum-based chemotherapy.

Clinical management

Treatment pathway and positioning

3.2 People with recurrent or metastatic cervical cancer, for whom chemotherapy is suitable, usually have platinum-based chemotherapy with paclitaxel, with or without bevacizumab. People whose cancer is PD-L1 positive (combined positive score [CPS] of 1 or more) usually also have pembrolizumab (see NICE's technology appraisal guidance on pembrolizumab plus chemotherapy for persistent, recurrent or metastatic cervical cancer [TA939]). If the cancer progresses, people usually have

single-agent chemotherapy. Cemiplimab is licensed after platinum-based chemotherapy (with or without immunotherapy). The company positioned cemiplimab specifically for people who have not had immunotherapy. This is narrower than the marking authorisation for cemiplimab but in line with the key clinical trial. At the committee meeting, the clinical experts agreed with the company's positioning. They added that cemiplimab should be used according to the trial evidence and noted that the trial included people who had not had immunotherapy. So, it was unknown if people will benefit from cemiplimab if they have already had pembrolizumab. The committee agreed that the company's positioning of cemiplimab for people who have not had immunotherapy was appropriate. It concluded that there is an unmet need for new treatment options for this condition, particularly for people with PD-L1-negative cancer.

Comparators

3.3 The comparators in the final NICE scope included single-agent chemotherapy, best supportive care (BSC) and tisotumab vedotin (subject to NICE evaluation). But the company thought that single-agent chemotherapy was the only relevant comparator. In its submission, the company explained that BSC was not a comparator because people are not expected to be eligible for cemiplimab if active treatment with existing chemotherapy options is not suitable. The company added that tisotumab vedotin was not a comparator because it was not established clinical practice. It added that cemiplimab and tisotumab vedotin may also be used in different populations in clinical practice. Cemiplimab would be used by people who have not had immunotherapy, and tisotumab vedotin, would be used by people who have had immunotherapy. The EAG's clinical experts agreed that BSC was not a relevant comparator. The EAG noted that it was uncertain whether tisotumab vedotin would be considered a relevant comparator by the committee. This is because the outcome of the tisotumab vedotin evaluation and timing of final draft guidance publication was uncertain. The committee noted that section 1.3.3 of NICE's company submission user guide was recently

updated to specify that: "A potential comparator is one which has final guidance before the first committee meeting for the appraisal of the intervention in question". The committee noted that final guidance for tisotumab vedotin had not been published at the time of the committee meeting for cemiplimab. On this basis, the committee concluded that tisotumab vedotin was not a relevant comparator and that single-agent chemotherapy was the only relevant comparator.

Clinical effectiveness

EMPOWER Cervical-1

3.4 The clinical-effectiveness evidence for cemiplimab came from the EMPOWER Cervical-1 trial. This was a phase 3, open-label, randomised controlled trial comparing cemiplimab (n=304) with investigator's choice of single-agent chemotherapy (n=304). It included people with recurrent or metastatic cervical cancer whose cancer had progressed after platinum-based chemotherapy. The primary efficacy endpoint was overall survival (OS). Key secondary efficacy endpoints included progression-free survival (PFS) and objective response rate. The company presented data from the final analysis of EMPOWER Cervical-1, with a data cut-off date of 03 October 2023 and a median follow-up of 47.3 months. Median OS was 11.7 months in the cemiplimab arm and 8.5 months in the chemotherapy arm (hazard ratio [HR] 0.67, 95% confidence interval [CI]: 0.56 to 0.80). Median PFS was 2.8 months in the cemiplimab arm and 2.9 months in the chemotherapy arm (HR 0.74, 95% CI: 0.62 to 0.88). At 24 months, an estimated 28.2% (95% CI: 23.0 to 33.5) of people in the cemiplimab arm were still alive, compared with 11.9% (95% CI: 8.4 to 16.1) in the chemotherapy arm. The committee noted that although median PFS in both treatment arms was similar, the curves diverged showing a longer-term benefit for cemiplimab. The committee concluded that EMPOWER Cervical-1 shows that cemiplimab improves OS and PFS compared with single-agent chemotherapy for people with recurrent or metastatic cervical cancer that has progressed after platinum-based chemotherapy. But it

noted some issues related to the trial's generalisability to the population expected to have cemiplimab in clinical practice (see section 3.5, section 3.6 and section 3.8).

Generalisability of EMPOWER Cervical-1

3.5 The EAG noted several issues related to the generalisability of EMPOWER Cervical-1. It noted that:

- The PD-L1 status in the trial population likely does not reflect the PD-L1 status in the population expected to have cemiplimab in clinical practice (see section 3.6).
- People with an Eastern Cooperative Oncology Group (ECOG) performance status above 1 were excluded from the trial, but the marketing authorisation for cemiplimab does not restrict treatment based on this.
- In the trial, 87.8% of people had progression within 6 months of completing platinum-based chemotherapy, which limits the generalisability to people who have progression more than 6 months after completing platinum-based chemotherapy.
- The trial did not include paclitaxel as one of the investigator's choice of single-agent chemotherapy regimens, when paclitaxel is a widely used second-line chemotherapy option in UK clinical practice.
- Time on treatment (ToT) for cemiplimab in the trial may not reflect clinical practice (see section 3.10).
- ToT for chemotherapy in the trial does not reflect clinical practice.

At the committee meeting, a clinical expert explained that people with an ECOG performance status of 2 or more may still benefit from treatment. They noted that the population is generally young and fit, and that ECOG performance status often improves on treatment. The NHS England Cancer Drugs Fund clinical lead explained that the Blueteq form is normally aligned with the trial inclusion criteria and would likely include only people with an ECOG performance status of 0 or 1, regardless of the

marketing authorisation wording. The company noted that paclitaxel was not included as a single-agent chemotherapy option in the trial because most people in the trial had paclitaxel as part of first-line treatment and their cancer had progressed on treatment. The company added that there is no gold-standard second-line treatment option and outcomes for all chemotherapy treatments are very similar. One clinical expert agreed that the treatment options used in EMPOWER Cervical-1 were similar to other cervical cancer trials, adding that they were in line with global National Comprehensive Cancer Network guidelines. They added that, outside of the UK, paclitaxel is not a commonly used second-line treatment. Regarding the time to progression after platinum-based chemotherapy, the company explained that 12.2% of people in EMPOWER Cervical-1 had disease progression more than 6 months after completing platinum-based chemotherapy. It added that there was still a benefit of cemiplimab in this group. A clinical expert explained that the cancer generally progresses within 6 months of first-line chemotherapy. The committee concluded that EMPOWER Cervical-1 was broadly generalisable to the population expected to have cemiplimab in clinical practice, but there were some issues around PD-L1 status and ToT (see section 3.6 and section 3.10).

PD-L1 status in EMPOWER Cervical-1 compared with clinical practice

3.6 The company positioned cemiplimab after platinum-based chemotherapy without immunotherapy with pembrolizumab (see section 3.2). This was aligned with the population in EMPOWER Cervical-1. The EAG noted that this meant that cemiplimab would predominantly be used by people whose cancer is PD-L1 negative. This is because people whose cancer is PD-L1 positive (CPS of 1 or more) would have had pembrolizumab at first line. This group would not be eligible for cemiplimab based on the company's positioning (see section 3.2). The EAG noted that EMPOWER Cervical-1 likely did not reflect PD-L1 status distribution in the population expected to have cemiplimab in clinical practice. This is because the trial recruited people irrespective of PD-L1 status. To address this, the

company presented subgroup analyses for PD-L1-positive and PD-L1-negative subgroups. It explained that results of these subgroup analyses showed a consistent benefit across both PD-L1-positive and PD-L1-negative subgroups. The results of the subgroup analyses are considered confidential by the company so cannot be reported here. It added that, although subgroup analyses results are available, the overall intention-to-treat [ITT] population should be considered because the subgroup analyses are underpowered and the marketing authorisation for cemiplimab is not restricted by PD-L1 status. The EAG further noted that the subgroup analyses are not representative of everyone in the trial. PD-L1 data was only obtained for a subset of people in the trial (371 out of 608), meaning PD-L1 status was not obtained for 39% of people recruited. It added that, of the cohort which did have PD-L1 status assessed, 36% had PD-L1-negative cancer in both trial arms. The EAG added that people recruited to the trial were not required to have PD-L1 status assessed before randomisation and could have PD-L1 status assessed based on historical tumour samples. It further added that PD-L1 status was not a stratification factor for randomisation and the subgroup analyses by PD-L1 status were not pre-specified. At the committee meeting, the clinical experts explained that PD-L1 testing is done on diagnosis using a punch biopsy. Both clinical experts agreed that people would not generally be re-biopsied at the time of recurrence or metastasis because testing is invasive and can result in delays to treatment. PD-L1 status in clinical practice is therefore based on historic samples. Clinical experts noted that PD-L1 status can change over time, but estimate that approximately 70% to 80% of tumours would be PD-L1 positive. They added that this is highly variable and depends on the centre or technique used to assess PD-L1 status. The committee considered the results of the subgroup analyses. It noted that cemiplimab targets PD-L1 so it could be considered unusual that it works equally well in people whose cancers are either PD-L1 positive or PD-L1 negative. The committee considered whether this was a genuine effect or a statistical quirk. One expert explained that this was not

a quirk of the data and cemiplimab has been shown to work irrespective of PD-L1 status in cutaneous squamous cell carcinoma. They added that there was also data from the compassionate use programme suggesting that cemiplimab worked equally well irrespective of PD-L1 status in cervical cancer. They added that this was also the case for pembrolizumab. The committee noted that there were limitations with using the PD-L1 subgroup data. These included that data was only available for a subset of the trial and analyses were post-hoc. It preferred to consider data from the ITT population of EMPOWER Cervical-1, but noted that this may overestimate the benefit in the predominantly PD-L1-negative population expected to have cemiplimab in practice.

Economic model

Company's modelling approach

3.7 The company's economic model adopted a partitioned survival approach including 3 mutually exclusive health states: pre-progression (which was further divided into 'on treatment' and 'off treatment'), post-progression, and dead. Health state occupancy was determined by parametric survival models for OS, PFS and ToT based on data from EMPOWER Cervical-1. The model used a lifetime time horizon of 33 years. A 1-week cycle length was chosen to accommodate the differing dosing schedules of chemotherapies. Because of the short cycle length, half-cycle correction was not applied. The committee concluded that the company's model structure was appropriate for decision making.

Modelling OS and PFS

3.8 The company used data from the ITT population of EMPOWER Cervical-1 to model OS and PFS in its base case. Independent generalised gamma parametric survival models were fitted for PFS and OS for each treatment arm. The company used independent models because it concluded that the proportional hazards assumption did not hold. As discussed in section 3.6, the company presented subgroup analyses based on PD-L1

status (positive and negative) for people with available PD-L1 status data from EMPOWER Cervical-1 (n=371). The company then explored a scenario in which survival curves were fitted to each subgroup separately, to provide a weighted incremental cost-effectiveness ratio (ICER), assuming that most people (96%) having cemiplimab in clinical practice would have PD-L1-negative cancer. In this scenario, generalised gamma curves were fit to PD-L1-positive and PD-L1-negative subgroup data. The company explained that the generalised gamma curve, used for the ITT population, was used because it provided one of the best fits for the PD-L1 subgroups. The company noted that the ICER was lower for this scenario than the ICER in its base case. The EAG noted that it was difficult, from the survival and hazard plots provided by the company, to determine the most appropriate curve for each subgroup. But the EAG noted that the company's generalised gamma curve provided the most optimistic long-term projection for OS in the PD-L1-negative subgroup. As discussed in section 3.6, the PD-L1 negative subgroup is the subgroup predominantly expected to have cemiplimab in clinical practice. To test the sensitivity of the ICER to alternative assumptions, the EAG used the alternative log-normal curve, which still provided a good statistical and visual fit to the data. The EAG noted that, with the alternative log-normal curve applied, the ICER increased compared with the ITT population. The committee noted that the EAG's scenario analysis showed that the ICER was sensitive to the modelling approach for the subgroups. The committee considered the plausibility of the subgroup analyses results. It concluded that it preferred to use the ITT population because of limitations with the subgroup data (see section 3.6). But, it added that this may not reflect survival in the PD-L1-negative subgroup that is most likely to have cemiplimab in clinical practice, resulting in uncertainty.

Modelling time on treatment

3.9 As with OS and PFS, the company used data from the ITT population of EMPOWER Cervical-1 to model ToT. The company used independent log-normal parametric survival models for cemiplimab and chemotherapy.

In the company's model, ToT was capped by PFS, which assumed that treatment is stopped at the time of disease progression. The EAG preferred to use the trial Kaplan–Meier data directly for both arms. It noted that the ToT curve for cemiplimab abruptly decreased at 96 weeks. This was because people in EMPOWER Cervical-1 had up to 16 cycles of cemiplimab treatment (each lasting 6 weeks). Because of the drop off after 16 cycles, the parametric model fits were generally poor. The EAG believed that, given the maturity of the ToT data for both arms, using a parametric model for ToT was unnecessary. The EAG also did not agree with the company's approach of capping ToT by PFS. It noted that 23% of people in the cemiplimab arm of EMPOWER Cervical-1 were considered by the trial investigators to have pseudoprogression. Pseudoprogression is when tumours appear to grow or new lesions appear on imaging scans, even though the treatment is actually working and the person's condition is clinically stable or improving. These people continued treatment beyond progression. So, the EAG preferred to remove capping in its base case to align with the trial. At the committee meeting, a clinical expert explained that they do see pseudoprogression in clinical practice, but this is more common with endometrial cancer and is rare in cervical cancer. They noted that if someone has a clinical response, they would continue treatment irrespective of what the scans show. The company explained that many people continuing treatment after progression in EMPOWER Cervical-1 only continued for 1 to 2 weeks. The committee noted that the different approaches used by the company and EAG to model ToT in their base cases only had a small impact on the ICER. The committee concluded that it preferred to not cap ToT by PFS, to reflect the trial data and clinical practice. Regarding the choice of Kaplan–Meier data or parametric model for ToT, the committee noted that all of the parametric models had a poor fit to the Kaplan–Meier data for ToT because of the drop in the Kaplan–Meier curve after 16 cycles. The committee was reassured that the EAG had explored the uncertainty around the Kaplan–Meier data adequately by using bootstrapping within its probabilistic

sensitivity analysis. So, the committee concluded that it preferred to use the Kaplan–Meier data for modelling ToT with bootstrapping to capture uncertainty.

Time on treatment in EMPOWER Cervical-1 compared with clinical practice

3.10 The company used data from EMPOWER Cervical-1 to model ToT (see section 3.9). But the EAG was concerned that ToT for cemiplimab in the trial may not reflect clinical practice. In EMPOWER Cervical-1, cemiplimab treatment was restricted to 16 cycles (each lasting 6 weeks). This was equivalent to 96 weeks of uninterrupted treatment. If treatment was delayed or interrupted, people in the trial could continue treatment for longer than 96 weeks until they completed all 16 cycles. The maximum treatment duration in the trial was 107.7 weeks. But the summary of product characteristics for cemiplimab states that it may be continued until disease progression or unacceptable toxicity. The EAG explained that its clinical experts would be reluctant to stop treatment if the cancer had not progressed and treatment was still tolerated. So, the EAG was concerned that, in clinical practice, ToT could be longer and the cost of treatment could be higher than estimated by the company based on EMPOWER Cervical-1 data. The EAG acknowledged that extending treatment duration could provide further benefit in terms of OS and PFS. But it noted that the size of the potential benefit is unknown, meaning the impact on the ICER is uncertain. In response to a request from the EAG, the company provided a scenario in which ToT data was re-censored at 96 weeks and curves fitted to the re-censored data to extrapolate ToT beyond 96 weeks. It noted that this approach provided a pessimistic 'worst-case scenario' because it included the additional cost of treatment beyond 96 weeks without adjusting the OS and PFS estimates to allow for any potential benefit. At the committee meeting, the clinical experts explained that, in clinical practice, healthcare professionals are familiar with using a fixed treatment duration for immunotherapies. They added that, on starting treatment, people would be informed of the maximum

treatment duration. The committee thought that if someone's cancer was still responding to treatment after 16 cycles, then they would likely have a strong preference to continue treatment. But it noted that there was no evidence available for OS or PFS if treatment continued. It noted that the company's scenario (in which treatment continued) considerably increased the ICER, but if there was a survival benefit of treatment beyond 16 cycles, then this scenario would not accurately capture health effects. The committee noted that including a stopping rule, specifying that cemiplimab treatment should stop after 16 cycles (each lasting 6 weeks), was in line with the clinical-effectiveness data from the trial. It noted that the company's cost-effectiveness model also reflected the costs and health effects of cemiplimab continued until progression, toxicity or a maximum of 16 cycles. It also noted that including a stopping rule for cemiplimab would be aligned with the approach used for other immunotherapies in cervical cancer (pembrolizumab [TA939]). The committee concluded that a stopping rule after 16 cycles should be included in the recommendations.

Utility values

3.11 EMPOWER Cervical-1 collected data on health-related quality of life using the European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire – Core 30 items (EORTC QLQ-C30). The company mapped responses to EQ-5D-3L utility values. Pre-progression utilities were estimated separately for each treatment arm. The company explained that this was because there were statistically significant differences between treatment arms in the trial. The pre-progression utilities were 0.735 for cemiplimab and 0.622 for chemotherapy. The company added that its approach of using separate utilities for each treatment arm was consistent with the clinical expectation of poorer quality of life for people having chemotherapy. The post-progression utility for cemiplimab was 0.613. This was based on pooled data for both arms of EMPOWER Cervical-1. The company explained that this was because there were fewer data points available after progression compared with

before progression in the trial. The post-progression utility for chemotherapy was assumed by the company to be equivalent to the proportional reduction in utility on progression for cemiplimab. This resulted in a post-progression utility for chemotherapy of 0.519. The company stated that using the pooled post-progression utility for chemotherapy of 0.613 lacked face validity because it was similar to pre-progression utility for chemotherapy of 0.622. The company further noted that some adverse events associated with chemotherapy, such as peripheral neuropathy, continue after stopping treatment so have a persistent impact after progression. The EAG was satisfied with the company's decision to use treatment-dependent pre-progression utilities. But it noted that it may be incorrect to assume the same proportionate decrement associated with progression in both treatment arms. It noted that the utility difference between arms may not persist after progression because most chemotherapy adverse events do not continue when treatment is stopped. So, the EAG base case used a pooled post-progression utility value from EMPOWER Cervical-1 of 0.613 for both arms, maintaining separate pre-progression utilities as per the company's base case. The clinical experts at the committee meeting explained that they would expect people to be fitter after cemiplimab than after chemotherapy. They added that people having chemotherapy may not recover as well as people having cemiplimab and may have a higher disease burden. The committee noted that the company's approach was likely optimistic. But it noted that the company's and EAG's alternative approaches had little impact on the ICER so agreed to consider both approaches in its decision making.

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 technology appraisal and highly specialised technologies guidance manual. In both the company's and EAG's base cases, the calculated severity weight was 1.7. Using the committee's preferred assumptions (see section 3.14), the calculated severity weighting was 1.7. So, the committee concluded that a severity weight of 1.7 applied to the QALYs was appropriate.

Cost-effectiveness estimates

Company and EAG cost-effectiveness estimates

3.13 Because of the confidential commercial arrangement for cemiplimab, the exact cost-effectiveness estimates are confidential and cannot be reported here. The deterministic and probabilistic ICERs for cemiplimab in both the company's and EAG's base cases were lower than the range normally considered an acceptable use of NHS resources.

The committee's preferences

3.14 The committee's preferred assumptions were:

- including only single-agent chemotherapy as the relevant comparator (see section 3.3)
- using data from the ITT population of EMPOWER Cervical-1, but noting that this was uncertain (see section 3.6)
- using Kaplan–Meier data to model ToT with bootstrapping to capture uncertainty (see section 3.9)
- not capping ToT by PFS (see section 3.9)
- including a stopping rule for cemiplimab after 16 cycles (see section 3.10)
- considering both the company's and EAG's approaches to modelling utility (see section 3.11)
- applying a severity weight of 1.7 to the QALYs (see section 3.12).

With the committee's preferred assumptions applied, the ICER for cemiplimab was below £25,000 per QALY gained. The committee

understood that the modelling may not fully reflect the outcomes for the predominantly PD-L1 negative population it would be used for, and some scenarios implied a higher ICER in this group. But the committee concluded that the ICER for cemiplimab was likely to fall in a cost-effective range.

Other factors

Equality and health inequality

3.15 Submissions from stakeholders noted that there are higher rates of cervical cancer in more deprived areas. They added that screening rates are also lower among people from more deprived areas and that people are likely to have more advanced disease at diagnosis. The EAG noted that the company had not provided a specific analysis, such as a distributional cost-effectiveness analysis, demonstrating that recommending cemiplimab has the potential to reduce health inequalities. It added that these disparities are unlikely to be impacted by whether this technology is made available for this indication, because they are mostly associated with disease incidence or delayed diagnosis. The committee agreed that differences in prevalence and patient populations cannot usually be resolved in a technology appraisal. But the committee can consider whether a specific equality issue has a significant impact on access to treatments. The committee noted the disparities in care and unequal access to care based on specific demographics. Stakeholders also added that the incidence of cervical cancer is higher in non-White ethnic groups and in people who have emigrated from Africa, parts of Asia and Eastern Europe. The committee recognised that race is a protected characteristic under the Equality Act 2010. But the committee concluded that its recommendations would not affect people protected by the equality legislation any differently. So the committee agreed that this was not a potential equalities issue.

Uncaptured benefits

3.16 The committee considered whether there were any uncaptured benefits of cemiplimab. It did not identify additional benefits of cemiplimab not captured in the economic modelling. So the committee concluded that the benefits of cemiplimab had already been taken into account.

Conclusion

3.17 Clinical trial evidence shows that cemiplimab increases PFS and OS, compared with single-agent chemotherapy. In the trial, people had cemiplimab for a maximum of 16 cycles (each lasting 6 weeks). The company positioned cemiplimab as an option for people who have not had immunotherapy. When considering the condition's severity, and its effect on quality and length of life, the most likely cost-effectiveness estimates are within the range that NICE considers an acceptable use of NHS resources. So, cemiplimab can be used for treating recurrent or metastatic cervical cancer that has progressed on or after platinum-based chemotherapy in adults if:

- they have not had immunotherapy
- treatment is stopped after 16 cycles (each lasting 6 weeks), or earlier if the cancer progresses or if there is unacceptable toxicity.

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 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 recurrent or metastatic cervical cancer and the healthcare professional responsible for their care thinks that cemiplimab 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 A.

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

Chair, technology appraisal committee A.

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.

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