

**NATIONAL INSTITUTE FOR HEALTH AND CARE
EXCELLENCE**

Draft guidance

**Tisotumab vedotin for treating recurrent or
metastatic cervical cancer that has progressed
on or after systemic treatment**

The Department of Health and Social Care has asked the National Institute for Health and Care Excellence (NICE) to produce guidance on using tisotumab vedotin 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?

Note that this document is not NICE's final guidance on tisotumab vedotin. 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- After considering these comments, the committee will prepare the final draft guidance.
- Subject to any appeal by stakeholders, the final draft guidance may be used as the basis for NICE's guidance on using tisotumab vedotin in the NHS in England.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: [Day month year]
- Second evaluation committee meeting: 14 April 2026
- Details of the evaluation committee are given in section 4

1 Recommendations

- 1.1 Tisotumab vedotin should not be used to treat recurrent or metastatic cervical cancer that has progressed on or after systemic treatment in adults.
- 1.2 This recommendation is not intended to affect treatment with tisotumab vedotin 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

Tisotumab vedotin is not required to be funded and should not be used routinely in the NHS in England for the condition and population in the recommendations.

This is because there is not enough evidence to determine whether tisotumab vedotin is value for money in this population.

Why the committee made these recommendations

Usual treatment for metastatic or cervical cancer that has progressed on or after systemic treatment is single-agent chemotherapy.

Clinical trial evidence shows that tisotumab vedotin increases how long people have before their cancer gets worse, and how long they live, compared with the trial investigator's choice of chemotherapy.

There are concerns about the economic model, including:

- its structure

- the modelling of how long people have before their condition gets worse and how long they live.

Because of the uncertainties in the economic model, it is not possible to determine the most likely cost-effectiveness estimates for tisotumab vedotin. So, it should not be used.

2 Information about tisotumab vedotin

Marketing authorisation indication

- 2.1 Tisotumab vedotin (Tivdak, Genmab) is indicated for ‘the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after systemic therapy’.

Dosage in the marketing authorisation

- 2.2 The dosage schedule is available in the [summary of product characteristics for tisotumab vedotin](#).

Price

- 2.3 The list price for tisotumab vedotin has not yet been approved. The company have provided an anticipated list price, which is considered confidential until it has been approved.
- 2.4 The company has a commercial arrangement, which would have applied if tisotumab vedotin had been recommended.

Carbon Reduction Plan

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

3 Committee discussion

The [evaluation committee](#) considered evidence submitted by Genmab, 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 the condition

- 3.1 Cervical cancer develops when abnormal cells in the lining of the cervix grow in an uncontrolled way and form a tumour. The 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. The clinical experts noted that recurrent or metastatic cervical cancer often affects young people, and they may have young children. A patient expert said that cervical cancer leads to a substantial disruption to quality of life, and that living with the condition is physically and emotionally exhausting. They also highlighted that the 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 who progress after first-line systemic treatment, there are limited treatment options available for this type of cancer. The main aims of treatment are to relieve symptoms and improve quality of life, and to extend life. A patient expert noted that the fear of recurrence and uncertainty about the future can feel overwhelming. The committee noted that there is a high disease burden for people with recurrent or metastatic cervical cancer with disease progression on or after systemic treatment. It concluded that there is an unmet need for treatment options after disease progression on or after systemic treatment.

Clinical management

Treatment pathway and comparators

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 usually also have pembrolizumab with chemotherapy (see [NICE's technology appraisal guidance on pembrolizumab with platinum-based chemotherapy for recurrent, persistent or metastatic cervical cancer](#)). Although [NICE's technology appraisal guidance on topotecan for the treatment of recurrent and stage 4B cervical cancer](#) recommends topotecan, it is not frequently used in clinical practice. The clinical experts explained that, for second-line treatment of recurrent or metastatic cervical cancer, people usually have single-agent chemotherapy. These include, but are not limited to, topotecan, vinorelbine, gemcitabine, irinotecan, pemetrexed and paclitaxel. In line with its marketing authorisation, the company positioned tisotumab vedotin as a treatment for recurrent or metastatic cervical cancer with disease progression on or after systemic treatment in adults. Based on this positioning, the company included single-agent chemotherapy as the comparator.

The EAG's clinical experts advised that retreatment with platinum doublet chemotherapy is commonly used as a second-line treatment. So, the EAG questioned whether platinum doublet chemotherapy should also be included as a comparator. The company said that platinum doublet chemotherapy retreatment has not been specifically studied in cervical cancer. It also said that it had not been mentioned by healthcare professionals at its UK Cervical Cancer advisory board. But the company acknowledged that, in a subsequent survey in England, 5 of 8 healthcare professionals said they would consider platinum doublet chemotherapy retreatment for some people as a second-line treatment.

The clinical experts at the committee meeting explained that platinum

doublet chemotherapy would usually be used in a different clinical scenario to tisotumab vedotin and single-agent chemotherapy. They explained that, because of the associated toxicities, retreatment with platinum doublet chemotherapy would be considered in people who are generally fit and have had a sufficiently long interval without chemotherapy. They added that they would consider tisotumab vedotin and single-agent chemotherapy after platinum doublet retreatment. One of the clinical experts also said that, in about 90% of people with recurrent or metastatic cervical cancer, the condition progresses within a year of first-line treatment. So, very few people would be considered for retreatment with platinum doublet chemotherapy. The committee acknowledged the differing clinical scenarios. It concluded that the company's positioning of tisotumab vedotin was appropriate and that single-agent chemotherapy was the appropriate comparator.

Clinical effectiveness

InnovaTV 301

3.3 The primary clinical evidence for tisotumab vedotin came from the [InnovaTV 301](#) trial. This is an ongoing global randomised open-label phase 3 trial comparing tisotumab vedotin (n=253) with investigator's choice chemotherapy (n=249). It has recruited people with recurrent or metastatic cervical cancer who have had 1 or 2 prior lines of systemic treatment. The primary efficacy endpoint is overall survival (OS), defined as the time from randomisation to the date of death from any cause. The key secondary efficacy endpoint is progression-free survival (PFS), defined as the time from randomisation to the first documentation by the investigator of disease progression, or to the date of death from any cause, whichever occurred first. At the time of the primary analysis, based on a data cutoff date of July 2023, median OS was 11.5 months in the tisotumab vedotin arm and 9.5 months in the chemotherapy arm in the intention-to-treat population (hazard ratio [HR] 0.70, 95% confidence interval [CI] 0.54 to 0.89). Median PFS was 4.2 months in the tisotumab

vedotin arm and 2.9 months in the chemotherapy arm (HR 0.67, 95% CI 0.54 to 0.82). The company also did an ad-hoc follow-up analysis for OS and PFS in January 2024, which has been incorporated into the economic model. But the results are considered confidential by the company and cannot be reported here. The committee concluded that tisotumab vedotin improves OS and PFS for people with recurrent or metastatic cervical cancer who have had 1 or 2 prior lines of systemic treatment.

Eye-care management plan

3.4 The committee was aware that, in the US, tisotumab vedotin has a black box warning for ocular toxicity. In the safety analysis population in [InnovaTV 301](#), 52.8% of people (132 of 250) in the tisotumab vedotin arm had an ocular treatment-emergent adverse event compared with 6.3% (15 of 239) in the chemotherapy arm. Of people who had an ocular adverse event in the tisotumab vedotin arm, 69.7% had resolution of or improvement in all symptoms, with 24.2% having resolution or improvement in some symptoms. The company provided an eye-care management plan and said that this would form part of the UK management strategy for tisotumab vedotin. It noted that this was aligned with the recommendations in the [summary of product characteristics for tisotumab vedotin](#). The eye-care management plan:

- states that an eye-care professional should carry out an ophthalmic examination before the first infusion, and then as clinically needed
- states that the treating healthcare professional should inspect the patient's eyes before each infusion, and identify whether they have any ocular signs and symptoms that need referral to an eye specialist
- provides a schedule for administration of 3 different eye drops during the treatment period
- states that cooling eye pads should be applied before starting the infusion, and used during and for 30 minutes after the infusion
- states that contact lenses should be avoided during treatment unless an eye-care professional advises otherwise.

The EAG noted that the approach for managing ocular adverse events in InnovaTV 301 seemed to align with the eye-care management plan provided by the company. But the EAG's clinical experts raised concerns about implementing the eye-care management plan in clinical practice. They stated that there are no facilities in oncology to carry out eye examinations and that this is not normally done before chemotherapy. The EAG's clinical experts also pointed out that the eye examinations, especially before treatment, would have to be done by an eye-care professional. Also, they stated that oncologists may not be familiar enough with the signs and symptoms that should prompt referral for specialist assessment. The EAG's clinical experts thought that, if tisotumab vedotin were recommended, eye departments would not have available resources to manage referrals for eye assessments before and during treatment. Overall, the EAG was advised that eye-care needs associated with tisotumab vedotin could present a barrier to introducing the treatment into a centre.

The committee was aware that eye-care management costs were included in the model. But it considered whether there may be implementation issues associated with introducing tisotumab vedotin into clinical practice. One of the clinical experts at the committee meeting said that they had recruited participants for InnovaTV 301. They explained that everyone had a baseline ophthalmic examination, and people who had tisotumab vedotin were referred to an eye specialist if new or worsening ocular symptoms developed. Overall, the clinical expert said that it was possible to manage ocular adverse events within the trial. They added that tisotumab vedotin is an antibody–drug conjugate and that other antibody–drug conjugates have similar ocular adverse events. So, the management pathway for these treatments is currently being developed in NHS clinical practice. The clinical experts thought that people will also be compliant with the

eyedrops included in the eye-care management plan if they are appropriately counselled by healthcare professionals.

The Cancer Drugs Fund clinical lead explained that the need for ophthalmic monitoring has been burdensome for ophthalmology departments in the NHS because of a lack of capacity. But they acknowledged that the population who will have tisotumab vedotin is smaller compared with other treatments that need similar monitoring. They added that some companies fund a scheme to manage eye-care in the community rather than secondary care. The company confirmed that it had not planned to provide such funding for tisotumab vedotin. But it also confirmed that the baseline eye examination can be done by an eye-care specialist, so could also be done outside of secondary care by a community optician. The committee noted that the company estimated an eligible patient population of 117 people in England. The committee concluded that, because the relevant patient population would be relatively small, it may be possible to implement the eye-care management plan within current clinical practice. But it acknowledged the impact that this would have on ophthalmology services.

Economic model

Company's modelling approach

3.5 The company presented a semi-Markov model with a time horizon of 30 years and a 1-week cycle length. The model comprised 3 mutually exclusive health states: progression free, progressed disease and death. All people were assumed to enter the model in the progression-free health state. From here, they could either remain in that health state, transition to the progressed-disease health state or transition to the death health state. From the progressed-disease health state, people could either remain in that health state or transition to the death health state. Transition probabilities between the 3 health states were estimated from [InnovaTV 301](#) trial data, using a parametric multistate modelling approach. The

company then combined transition probabilities to reconstruct estimates of PFS and OS, which were used to calculate health-state occupancy in the model. The company used InnovaTV 301 Kaplan–Meier (KM) data to directly estimate OS during the first 12 months, followed by extrapolations based on the parametric multistate distributions (see [section 3.7](#)).

Model structure and post-progression survival

3.6 The company said that it chose a semi-Markov model, rather than a partitioned survival model (PSM). In state-transition models such as a semi-Markov model, health-state occupancy is estimated by applying a set of transition probabilities. These inform the movement of people between health states within each set time period. A PSM directly uses PFS and OS curves to estimate health-state occupancy. The company chose a semi-Markov model because it allowed the assumption that risk of death after progression is constant, and the same in the tisotumab vedotin and chemotherapy treatment arms. Specifically, the company assumed an exponential hazard for post-progression survival, with the same hazard applied in both treatment arms. It estimated this rate using individual-level patient data on post-progression survival, pooled from the tisotumab vedotin and chemotherapy arms of [InnovaTV 301](#). It explained that it had explored a PSM but this overestimated survival in the chemotherapy arm. For example, at 2 years, the PSM predicted survival of 16% to 20% for chemotherapy compared with 10% to 13% from clinical expert advice and evidence from [McLachlan et al. \(2017\)](#). The company noted that, in the PSM, there was an extended tail in the OS chemotherapy arm and overlap in the OS curves between arms. This meant that some people having chemotherapy remained alive for a long time after the data cutoff timepoint. Also, that there was a higher proportion of people alive in the chemotherapy arm than in the tisotumab vedotin arm at certain timepoints. It said that this was likely because of random variation rather than a genuine survival benefit for chemotherapy because few people remained at risk.

The EAG had concerns about the company's use of a semi-Markov model because it did not think that the InnovaTV 301 data supported the assumptions of a constant post-progression mortality rate. It noted that the hazard plot for post-progression survival pooled across treatment arms show a time-varying hazard function (rather than a constant hazard). Also, the goodness-of-fit statistics (Akaike information criterion and Bayesian information criterion values) for the standard parametric distributions fitted to post-progression survival data from InnovaTV 301 showed that other distributions provided a better fit than the exponential distribution. The EAG noted that assuming the same post-progression survival hazard for tisotumab vedotin and chemotherapy may underestimate or overestimate OS if post-progression mortality risk differs between treatment arms. But the EAG was not able to override the assumption of a constant post-progression mortality risk in the company's model. This was because the model did not include 'tunnel states', which would retain information about the time of progression. The EAG preferred to use a PSM, with log-logistic extrapolations for OS (and PFS), independently fitted in each arm. It said that it preferred the log-logistic extrapolation because of statistical and visual fit to trial data. It also preferred to assume that the risk of mortality was the same in both treatment arms from the point where the OS curves converged at about 45 months.

The committee agreed that the hazard plot did not support the assumption of a constant post-progression mortality. It also agreed that other distributions showed better statistical fit compared with the exponential distribution. It also noted that the semi-Markov model was restricted to using the exponential distribution to estimate post-progression survival because of the absence of tunnel states. It thought that this was a limitation in the company's model structure. But it acknowledged that adding tunnel states to the model would add complexity. It noted that this limitation could be overcome by using a PSM. It also noted that the

extrapolations within the PSM were based on InnovaTV 301. So, if the chemotherapy arm in a PSM had higher OS than would be expected in clinical practice, the same might also apply to tisotumab vedotin. The company agreed that this may be the case. It said that, compared with the InnovaTV 301 data and estimates generated using a PSM, its modelling approach led to more conservative OS estimates for both chemotherapy and tisotumab vedotin. The committee acknowledged this but thought this limitation could be addressed by using appropriate parametric curves within a PSM. Overall, the committee was minded to prefer a PSM structure. It noted that the log-logistic distribution, which was preferred by the EAG, resulted in the most optimistic survival extrapolations for chemotherapy of all the standard parametric distributions. It thought that the log-logistic distribution did not appear to fit the observed trial data well. It said that further information from the company about the validity of different extrapolations within the PSM would be useful. It requested that the company explore the different standard parametric distributions within a PSM for PFS and OS. It requested information about validity of the distributions, including assessment of:

- visual fit to observed KM data from InnovaTV 301
- the underlying hazard functions over time and validation by clinical experts
- the clinical plausibility of extrapolations
- goodness-of-fit statistics.

OS assumptions

3.7 The company estimated transition probabilities between the 3 health states in the semi-Markov model using a parametric multistate modelling approach (see [section 3.5](#)). But, for the first 12 months, it did not use modelled estimates based on transition probabilities to the death health state. Rather, it used KM data from [InnovaTV 301](#) to override modelled OS predictions for the first 12 months. The company said that it chose this approach because empirical inspection and clinical validation:

- showed that the fitted curves overestimated OS for chemotherapy
- underestimated OS for tisotumab vedotin.

It noted that the OS KM curves for the treatment arms overlapped and attributed this to random variation because of diminishing sample size. The exact timepoint at which the OS KM curves converged is considered confidential by the company and cannot be reported here. The company said that, at 12 months, the number of people at risk was still meaningful. But, beyond this point, the number at risk changed substantially. So, it viewed that the 12-month cutoff was appropriate because it maximised the use of robust empirical data before applying the fitted curves. The EAG agreed that the overlap of the KM OS curves was likely because of the diminishing sample size. But it noted that the diminishing sample size applied in both arms. It said that an alternative interpretation of the OS results from the trial was that the survival advantage of tisotumab vedotin waned and did not persist beyond the point where the KM curves converged. Also, it thought that there was a risk of bias from:

- the company's post-hoc decision to use KM data to override the model predictions, and
- the choice of timepoint to switch from KM to the fitted curves.

So, the EAG preferred not to use KM data to override OS model predictions for the first 12 months in its base case. The committee recalled that it requested further information about the validity of standard parametric distributions within a PSM for OS (see [section 3.6](#)). It noted the risk of bias associated with using direct KM curves highlighted by the EAG. So, the committee had a preference to use extrapolated curves over directly using KM data, if further exploration of OS curves provided reliable estimates of OS.

Extrapolations of time to progression and pre-progression survival

3.8 As part of its parametric multistate modelling approach, the company chose a generalised gamma distribution for time to progression for both treatment arms. For pre-progression survival, the company used a Gompertz distribution for tisotumab vedotin and a log-normal distribution for chemotherapy. It said that its choice of distributions was based on:

- visual fit to the observed KM data
- clinical plausibility of the long-term extrapolations
- statistical goodness of fit to the observed data.

It also assessed the underlying hazard functions over time and clinical plausibility of hazard assumptions. The EAG said that the extrapolations for time to progression were uncertain because of the periodic timing of assessments and the diminishing sample size. For pre-progression survival, the EAG thought that there was a high degree of uncertainty over the extrapolations. This was because of the low numbers of observed events (that is, deaths before progression) in [InnovaTV 301](#). To explore the sensitivity of the incremental cost-effectiveness ratio (ICER) to time to progression, and pre-progression survival distributions, the EAG did scenario analyses with alternative distributions. This showed that the ICER was sensitive to the choice of time-to-progression extrapolation. But the choice of pre-progression survival extrapolation had a limited impact in the company's base case model. This was because the company applied KM OS data directly for the first 12 months (see [section 3.7](#)), and most patients had progressed by month 12. The committee recalled the uncertainty associated with the company's assumptions about post-progression survival in the semi-Markov model (see [section 3.6](#)). It thought that the diminishing sample size, especially beyond month 12, may have caused some uncertainty with the time-to-progression extrapolations. But it noted that the pre-progression survival extrapolations were highly uncertain

because of the low number of observed events in InnovaTV 301. It concluded that the pre-progression survival extrapolations added further uncertainty to the cost-effectiveness analysis using the semi-Markov model.

Administration cost for paclitaxel

3.9 Paclitaxel was not included in the chemotherapy arm of [InnovaTV 301](#) but the company included it for costing single-agent chemotherapy in the economic model. This was because the company's clinical experts advised that paclitaxel is commonly used as a second-line treatment in recurrent or metastatic cervical cancer. The company assumed that all treatments were administered in an outpatient setting and used administration costs from NHS reference costs. In its submission, the company assumed a higher cost for administration of paclitaxel than for the other single-agent chemotherapies. For paclitaxel, it assumed an administration cost code of SB14Z, based on delivery for 'complex' chemotherapy with a prolonged infusion. For the other single-agent chemotherapies, it assumed a lower administration cost based on a cost code for 'simple' chemotherapy (SB12Z). The company later provided additional data to support using a different administration cost code (SB13Z). This was based on 2 NHS protocols for administration of single-agent paclitaxel, the NHS payments scheme for 2025/2026 and the National Tariff Chemotherapy Regimens workbook 2017/2018.

The EAG's clinical experts advised the EAG that single-agent paclitaxel is typically administered as a relatively short infusion (around 1 hour). So, the costs should not differ from those for other chemotherapies. So, the EAG preferred to use the SB12Z cost code. The Cancer Drugs Fund clinical lead said that, for weekly paclitaxel, the SB13Z cost code would be used. This is because the SB13Z cost code would cover the time need to cannulate someone, administer the necessary premedication and the paclitaxel, flush the line and then remove the cannula. They added that more up-to-date costs for the relevant administration costs are now

available compared with the costs used in the model. The committee concluded that it preferred to use the SB13Z cost code for the administration of weekly paclitaxel. It also requested the company to update the chemotherapy administrations costs with the latest NHS reference costs available.

Severity

3.10 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 quality-adjusted life years (QALYs; a severity modifier) 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 technology appraisal and highly specialised technologies guidance: the manual](#). The committee noted that the QALY shortfall estimates were dependent on the total QALYs in the chemotherapy arm of the model. It also noted that further information was needed for it to decide on its preferred modelling assumptions (see [section 3.13](#)) and so the appropriate severity modifier.

Cost-effectiveness estimates

Company and EAG cost-effectiveness estimates

3.11 Because of the confidential commercial arrangements for the prices of tisotumab vedotin, the comparators and other treatments in the model, the exact cost-effectiveness estimates are confidential and cannot be reported here. The deterministic and probabilistic ICERs for tisotumab vedotin in the company's base case were higher than the range normally considered an acceptable use of NHS resources. The deterministic and probabilistic ICERs for tisotumab vedotin in the EAG's base case were considerably higher than the range normally considered an acceptable use of NHS resources.

Uncertainties

3.12 [NICE technology appraisal and highly specialised technologies guidance: the manual](#) 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 (see [section 3.16](#)). The committee noted the high level of uncertainty about:

- the impact that implementing the eye-care management plan for tisotumab vedotin would have on ophthalmology services (see [section 3.4](#))
- the semi-Markov model structure and the assumptions that the risk of death after disease progression is constant, and the same in both treatment arms (see [section 3.6](#))
- the use of direct KM data to override fitted OS curves (see [section 3.7](#))
- the pre-progression survival extrapolations (see [section 3.8](#)).

The committee's preferences and request for additional analysis

3.13 For the cost-effectiveness analysis, the committee preferred using the SB13Z cost code for the administration of weekly paclitaxel. The committee also requested that the company use updated chemotherapy administration costs using the latest NHS reference costs available (see [section 3.9](#)). The committee could not determine the most plausible ICER without further analyses so could not recommend tisotumab vedotin for routine use in the NHS. It requested:

- further information about the validity of the standard parametric distributions, within a PSM structure for PFS and OS (see [section 3.6](#))
- updated chemotherapy administration costs using the latest NHS reference costs available (see [section 3.9](#)).

Managed access

- 3.14 Having concluded that tisotumab vedotin could not be recommended for routine use in the NHS, the committee considered whether it could be recommended for use during a managed access period. It noted that the company had not provided a managed access proposal and that there was not yet a plausible cost-effectiveness estimate. So, a recommendation with managed access was not an option.

Other factors

Equality

- 3.15 The company noted that cervical cancer rates are 65% higher in the most deprived quintile compared with the least deprived quintile. It added that screening rates are lower among people from more deprived areas. Also, uptake for the human papillomavirus vaccine is lower in more deprived areas and in non-White ethnic groups. A patient expert also noted that access to new treatments can be unequal, with geographic, financial and cultural factors affecting access. 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. But, because its recommendation does not restrict access to treatment for some people over others, the committee agreed these were not potential equalities issues.

Uncaptured benefits

- 3.16 The company noted that cervical cancer often affects young people with children and that even small improvements in survival would allow them to spend more time with their families. A clinical expert noted that paclitaxel, one of the comparator treatments, is given weekly and that weekly administration may be limiting for people with difficulty accessing transport. In comparison, tisotumab vedotin is given every 3 weeks, so

may be beneficial for these people. A clinical expert also noted that tisotumab vedotin treatment may be associated with societal benefits. This is because, in their experience, people with recurrent or metastatic cervical cancer can return to work if they are well enough. The committee concluded that it would take into account any potential uncaptured benefits when considering the most appropriate ICER threshold.

Conclusion

3.17 The committee agreed that further information was needed before it could decide on all of its preferred modelling assumptions and understand the full impact of the uncertainties. So, it was unable to establish that tisotumab vedotin was a cost-effective use of NHS resources. It concluded that tisotumab vedotin should not be used for recurrent or metastatic cervical cancer that has progressed on or after systemic treatment in adults.

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 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

Radha Todd

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.

Dilan Savani

Technical lead

Caron Jones

Technical adviser

Jennifer Upton

Project manager

Lizzie Walker

Principal technical adviser

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