National Institute for Health and Care Excellence

Health Technology Evaluation

Tislelizumab with chemotherapy for untreated recurrent or metastatic nasopharyngeal cancer [ID6304]

Response to stakeholder organisation comments on the draft remit and draft scope

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: the draft remit and proposed process

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	BeOne Medicines	BeOne considers that it is appropriate for NICE to evaluate this topic. We consider the most appropriate route of evaluation is the Single Technology Appraisal route.	Thank you for your comment. No action needed.
	British Association of Head & Neck Oncologists	Single technology appraisal - appropriate	Thank you for your comment. No action needed.
Wording	BeOne Medicines	The wording of the remit should reflect the entirety of the UK marketing authorisation for tislelizumab in this indication: "*Tevimbra in combination with gemcitabine and cisplatin is indicated for the first-line treatment of adult*	Thank you for your comment. The remit has been amended to

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		patients with recurrent, not amendable to curative surgery or radiotherapy, or metastatic nasopharyngeal cancer."	include that tislelizumab with chemotherapy is being appraised for the first-line treatment of recurrent nasopharyngeal cancer that cannot be treated with curative surgery or radiotherapy, or metastatic nasopharyngeal cancer.
	British Association of Head & Neck Oncologists	The term 'untreated recurrent or metastatic nasopharyngeal cancer' is potentially confusing. Description of the technology as 1st line treatment for recurrent or metastatic NPC would be less ambiguous.	Thank you for your comment. The remit has been amended to include that tislelizumab with chemotherapy is being appraised for the first-line treatment of recurrent nasopharyngeal cancer that cannot be treated with curative surgery or radiotherapy, or metastatic nasopharyngeal cancer.
Timing	BeOne Medicines	There is a significant unmet need in this population. Currently, there are no NICE-approved pharmacological options for the treatment of untreated recurrent or metastatic nasopharyngeal cancer (NPC) and therefore there is an urgent need for new treatment options.	Thank you for your comment. No action needed.

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	British Association of Head & Neck Oncologists	Non urgent	Thank you for your comment. No action needed.
Additional comments on the draft remit	BeOne Medicines	None	Thank you for your comment. No action needed.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	BeOne Medicines	Tislelizumab (TEVIMBRA) was granted a UK marketing authorisation for this indication on 6 March 2026: "*Tevimbra in combination with gemcitabine and cisplatin is indicated for the first-line treatment of adult patients with recurrent, not amendable to curative surgery or radiotherapy, or metastatic NPC"*.	Thank you for your comment. The scope has been updated to state tislelizumab (Tevimbra, BeOne Medicines) in combination with gemcitabine and cisplatin is indicated for the first line treatment of recurrent, not amenable to curative surgery or radiotherapy, or metastatic nasopharyngeal cancer.
	British Association of	Details of treatment for this population are confusing and muddled as listed. It needs to be clearer that the population in question is that where no focal	Thank you for your comment. The scope

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	Head & Neck Oncologists	therapy (surgery, radiotherapy, chemoradiotherapy in all their forms) is not possible. The current treatment for this population is chemotherapy alone or best supportive care, not the options listed.	has been updated to state tislelizumab (Tevimbra, BeOne Medicines) in combination with gemcitabine and cisplatin is indicated for the first line treatment of recurrent, not amenable to curative surgery or radiotherapy, or metastatic nasopharyngeal cancer The population of the scope has been updated to state adults with first-line recurrent nasopharyngeal cancer that cannot be treated with curative surgery or radiotherapy, or metastatic disease. The comparators listed in the scope for this population is chemotherapy and best supportive care. No action needed.

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Population	BeOne Medicines	Please revise the description of the population to say: “Adults with untreated recurrent, not amenable to curative surgery or radiotherapy, or metastatic nasopharyngeal cancer”.	Thank you for your comment. The scope has been updated.
	British Association of Head & Neck Oncologists	See above	Thank you for your comment. The scope has been updated.
Subgroups	BeOne Medicines	There are no sub-groups, so far as we are aware.	Thank you for your comment. No action needed.
	British Association of Head & Neck Oncologists	No, no biomarkers validated to support sub-group stratification	Thank you for your comment. No action needed.
Comparators	BeOne Medicines	The current standard of care in the NHS for untreated recurrent or metastatic NPC is gemcitabine in combination with platinum-based chemotherapy, most usually cisplatin. Although 5FU, docetaxel or paclitaxel are used in the NHS to treat this indication, they are usually used in combination with one or more other treatments as part of a doublet or triplet treatment regimen or are given as adjuvant therapies. Monotherapy 5FU, docetaxel or paclitaxel would not be appropriate or relevant comparators for tislelizumab in this indication. Secondly, the current European Society for Medical Oncology (ESMO) clinical practice guidelines for first-line treatment of recurrent or metastatic NPC position 5FU, docetaxel, capecitabine and paclitaxel as second-line options only [Bossi et al., 2022], making them further unsuitable as comparators for tislelizumab in this first-line setting.	Thank you for your comment. The scope has been kept broad at this stage so 5FU, docetaxel, capecitabine, paclitaxel and best supportive care will remain as a comparator. Justification for choice of comparators can be made at submission stage.

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		Best supportive care is not considered to be an appropriate comparator and should be removed from the final scope.	
	British Association of Head & Neck Oncologists	Yes, but need to be cognisant of the parallel NICE appraisal of toripalimab with chemotherapy which is the most contemporary comparator. Also important to be aware of a 3rd immune check point inhibitor, camrelizumab, which also has proven efficacy in this setting with chemotherapy. Neither camrelizumab nor toripalimab currently used in UK	Thank you for your comment. Toripalimab is currently undergoing a NICE evaluation for the treatment of recurrent, not amendable to surgery or radiotherapy, or metastatic nasopharyngeal cancer. It has been added as a comparator, subject to NICE evaluation. Camrelizumab does not have a marketing authorisation in the UK for the treatment of recurrent or metastatic nasopharyngeal cancer and is not planned to undergo a NICE evaluation within the timelines of this evaluation, so will not be included as a comparator for this appraisal.

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Outcomes	BeOne Medicines	The outcomes listed are appropriate.	Thank you for your comment. No action needed.
	British Association of Head & Neck Oncologists	Yes, the outcomes are appropriate	Thank you for your comment. No action needed.
Equality	BeOne Medicines	There are potential equality issues which need to be considered when appraising a new treatment option for untreated, recurrent or metastatic NPC. These do not impact the remit or scope of the appraisal but have been included for awareness: NPC is a rare cancer that disproportionally affects Inuit populations and ethnic minorities (in particular, individuals of Chinese and African descent). NPC is more common in males than females currently, although the rates of NPC are increasing in females vs. males. People aged 65-69 years old, tobacco smokers and people who chew betel nut are all groups at higher risk of developing NPC.	Thank you for your comment. Any equality issues raised will be considered in the equality impact assessment and by committee.
	British Association of Head & Neck Oncologists	NPC, even in UK, is more prevalent in people of south china or north Africa descent but no barriers anticipated with equality of opportunity.	Thank you for your comment. Any equality issues raised will be considered in the equality impact assessment and by committee.
Other considerations	BeOne Medicines	None	Thank you for your comment. No action needed.

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	British Association of Head & Neck Oncologists	It is important to note that chemotherapy + immunotherapy has been the established standard of care in this clinical context for several years in the Far East and in the US, following publications of various phase 3 studies, including Rationale 309. Unfortunately equivalent patients in the UK have been limited to chemotherapy alone despite at least 3 trials demonstrating the benefit of adding an immune checkpoint inhibitor in this setting. There is therefore a significant unmet clinical need and inequity.	Thank you for your comment. No action needed.
Questions for consultation	BeOne Medicines	**Where do you consider tislelizumab will fit into the existing care pathway for untreated recurrent or metastatic nasopharyngeal cancer?** Tislelizumab in combination with gemcitabine and cisplation will be positioned as an alternative to chemotherapy alone as a first-line pharmacological option for previously-untreated recurrent or metastatic NPC, in accordance with its UK marketing authorisation. This positioning is also in accordance with the most recent ESMO clinical practice guidelines, which recommend gemcitabine-cisplatin-based regimens as the first-line medical therapy option for recurrent and/or metastatic NPC [Bossi et al., 2022]. **Please select from the following, will tislelizumab be:** **A. Prescribed in primary care with routine follow-up in primary care** **B. Prescribed in secondary care with routine follow-up in primary care** **C. Prescribed in secondary care with routine follow-up in secondary care** **D. Other (please give details):** **For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.**	Thank you for your comment. No action needed.

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		Tislelizumab would be prescribed in secondary care for this indication, with routine follow-up also provided in secondary care, in line with current standard of care chemotherapy. **Would tislelizumab be a candidate for managed access?** It is not currently anticipated that tislelizumab will be a candidate for managed access. **Do you consider that the use of tislelizumab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?** Patients with untreated recurrent or metastatic NPC have few treatment options, with no NICE-approved treatments available. The approval of tislelizumab by NICE would provide increased patient and clinician choice in this underserved treatment space, where surgery and/or radiotherapy are not suitable, or have failed. **Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.** Not applicable. **Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.**	

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		BeOne is not aware of any of the treatments included in the scope being used in practice differently from that advised in their SmPC.	
	British Association of Head & Neck Oncologists	Where do you consider tislelizumab will fit into the existing care pathway for untreated recurrent or metastatic nasopharyngeal cancer? ➢ As an alternative to 1st line palliative chemotherapy alone Please select from the following, will tislelizumab be: **C. Prescribed in secondary care with routine follow-up in secondary care** Same setting as comparators Would tislelizumab be a candidate for managed access? ➢ Yes Do you consider that the use of tislelizumab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation? ➢ No Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits. ➢ Published results of Phase 3 RATIONALE-309 study ➢ Yang Y, Pan J, Wang H, et al. Tislelizumab plus chemotherapy as first-line treatment for recurrent or metastatic nasopharyngeal cancer: A multicenter phase 3 trial (RATIONALE-309). *Cancer Cell*. 2023;41(6):1061-1072.e4. doi:10.1016/j.ccell.2023.04.014 ➢ Yang Y, Yen CJ, Pan J, et al. First-Line Tislelizumab Plus Chemotherapy for Recurrent or Metastatic Nasopharyngeal Cancer:	Thank you for your comment. No action needed.

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		Three-Year Follow-Up of the Phase 3 RATIONALE-309 Randomized Clinical Trial. JAMA Oncol. 2026;12(4):384-393. doi:10.1001/jamaoncol.2026.0020 While the primary endpoint was PFS rather than OS, the updated analysis also showed a clinically meaningful OS benefit. Importantly, cross over to tislelizumab in the control arm was allowed upon disease progression, otherwise the OS curves may have been more divergent. Tolerable toxicities, in the range expected with immunotherapy. Benefits were independent of PDL1 expression. PFS has similarly been used as the primary endpoint in other immunotherapy studies in this context. Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. ➢ No	
Additional comments on the draft scope	BeOne Medicines	None	Thank you for your comment. No action needed.
	British Association of Head & Neck Oncologists	Stakeholder list: Several organisations have no role in management or support of people with NPC. Geographical inequity of representation in both patient/carer groups and research groups	The stakeholder list is kept broad at the Scoping stage. No change needed. All stakeholder groups are national organisations in England.

The following stakeholders indicated that they had no comments on the draft remit and/or the draft scope

None