National Institute for Health and Care Excellence

Health Technology Evaluation

Pembrolizumab with enfortumab vedotin for neoadjuvant and adjuvant treatment of muscle-invasive bladder cancer [ID6607]

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	Action Bladder Cancer UK	It is highly appropriate for this topic to be evaluated. Treatment options for muscle invasive bladder cancer are limited – there are significant unmet needs within this patient group. A large percentage of this patient group are not eligible for current treatment The proposed route is acceptable (however, see note below re urgency).	Thank you for your comment. This evaluation has been scheduled into the Technology Appraisals work programme.
	MSD UK	The proposed evaluation route is appropriate.	Thank you for your comment. This evaluation has been scheduled into the Technology Appraisals work programme.

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	Fight Bladder Cancer	We agree that a single technology appraisal is appropriate. This combination for muscle-invasive bladder cancer in the peri-operative setting represents a significant potential change. Patients in this setting who are not eligible for cisplatin-based chemotherapy, or have a recurrence despite standard neoadjuvant treatment have a substantial unmet need, and a timely evaluation is important given the high risk of recurrence and death in this population of patients.	Thank you for your comment. This evaluation has been scheduled into the Technology Appraisals work programme.
	British Uro-Oncology Group	Appropriate	Thank you for your comment. This evaluation has been scheduled into the Technology Appraisals work programme.
Wording	The remit is appropriate	The remit is appropriate.	Comment noted.
	Fight Bladder Cancer	Yes	Comment noted.
	British Uro-Oncology Group	Appropriate	Comment noted.
Additional comments on the draft remit	Action Bladder Cancer UK	Patients and clinicians consider this new treatment to be of high importance to address the poor outcomes faced by this patient group. This treatment offers robustly-evidenced improvement on existing treatment options, and also provides a treatment option for many cases where there is currently no systemic treatment option available.	Thank you for your comment. No changes to the scope required.

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		The availability of effective treatment options for this patient group facing poor outcomes is of pressing need, thus has an urgency for the NHS. There is also a need for rapid action to consider and assimilate new advances in treatment of bladder cancer into the health system, and to adapt treatment pathways and workforce requirements as required. Due to the high recurrence rate, and likelihood of progression, together with continuing invasive monitoring, the lifetime treatment costs per patient of bladder cancer is the highest of all cancers.	
	MSD UK	The provisional scheduling for this topic is appropriate.	Thank you for your comment. No changes to the scope required.
	Fight Bladder Cancer	Muscle-invasive bladder cancer is an aggressive disease with a significant risk of recurrence after surgery. Delays in access to more effective peri-operative treatment could result in preventable metastatic progression. For a patient and their family, recurrence after having the huge surgery that is a radical cystectomy is both physically and psychologically devastating. Earlier access to more effective neoadjuvant/adjuvant options could reduce mortality for the patient and reduce the costs for the NHS that are associated with metastatic bladder cancer and its long-term morbidity	Thank you for your comment. No changes to the scope required.
	British Uro-Oncology Group	Complete evaluation as soon as possible in order to allow patient access to treatment	Thank you for your comment. No changes to the scope required.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Action Bladder Cancer UK	NOTE: the following information is missing from the Background. Whilst more men than women are diagnosed with bladder cancer, women are more likely to be diagnosed at a later stage. What is not included in the Background information, is the extremely high number of MIBC patients who are ineligible for treatment currently available. ABC UK feel that it is key to set this context accurately. It should be noted within the background note that nearly 50% of patients are cisplatin-ineligible, (older, frailer, and with greater comorbidities), and therefore currently without effective neoadjuvant options. This large group of patients will often proceed directly to surgery and demonstrate inferior outcomes.	Thank you for your comments. The background section of the scope has been updated.
	MSD UK	MSD suggest expanding the background information to clarify that MIBC is a potentially curative setting and that surgery or radiotherapy are radical treatments given with curative intent. MSD suggests also to include cisplatin eligibility criteria (e.g. age, fitness, renal function) and lack of treatment options for patients who are not eligible for cisplatin-based neoadjuvant chemotherapy. MSD suggest adding details relating to pembrolizumab under the technology section, as currently it includes information on enfortumab vedotin only.	Thank you for your comment. The background and technology sections of the scope have been updated.
	Fight Bladder Cancer	Yes	Comment noted.
	British Uro-Oncology Group	Background is accurate. NG2 considers systemic treatment (neoadjuvant and adjuvant chemotherapy) and definitive treatment (surgery or radiotherapy with radiosensitisation) separately. It is important to maintain this separation as they treat systemic disease and local disease respectively.	Thank you for your comments. No changes to scope needed.

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		Consideration of both aspects together will affect patients' autonomy in making a choice of definitive treatments.	
	Astellas	In the technology section, the first paragraph ('Enfortumab vedotin (Padcev, Astellas) does not currently have a marketing authorisation…'): this should be corrected to 'enfortumab vedotin with pembrolizumab', in line with the intervention listed in the draft scope table. Also in the technology section, paragraph two, an indication is missing – please update to: 'Enfortumab vedotin has two existing marketing authorisations in the UK: • In combination with pembrolizumab, for the first line treatment of unresectable or metastatic urothelial cancer in adults who are eligible for platinum-containing chemotherapy • As monotherapy, for the treatment of locally advanced or metastatic urothelial cancer in adults who have previously received a platinum-containing chemotherapy and a programmed death receptor-1 or programmed death-ligand 1 inhibitor	Thank you for your comment. The technology section of the scope has been updated.
Population	Action Bladder Cancer UK	Yes	Comment noted.
	MSD UK	The population is defined appropriately.	Comment noted.
	Fight Bladder Cancer	Yes, however we recommend explicitly stating cisplatin-eligibility versus cisplatin-ineligible patients for clarity	Thank you for your comment. Subgroups have been added to the draft scope.

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	British Uro-Oncology Group	Appropriate	Comment noted.
	AstraZeneca	Suggest aligning with previous appraisals as ID6168 for consistency 'Adults with resectable muscle-invasive bladder cancer'	Thank you for your comment. The scope has been written in line with current NICE style.
Subgroups	Action Bladder Cancer UK	Should be considered for all patients	Comment noted.
	MSD UK	Cisplatin-eligible and cisplatin-ineligible subgroups are relevant for this appraisal and are represented by the KEYNOTE-B15 (1) and KEYNOTE-905 (2) trials, respectively. Treatment options for cisplatin-eligible and cisplatin-ineligible patients differ, therefore comparators included in the clinical and cost-effectiveness analyses will differ.	Thank you for your comment – subgroups have been added to the scope.
	Fight Bladder Cancer	Older patients represent a significant proportion of the bladder cancer population, there may be differential clinical and cost effectiveness across these groups	Thank you for your comment. Issues related to differences in prevalence or incidence of a disease cannot be addressed in a technology appraisal.
	British Uro-Oncology Group	No	Comment noted.
	AstraZeneca	This section is missing in the draft scope. As this evaluation consists in a joint appraisal from previous ID6607 and ID6301, and the evidence is anticipated to rely in different pivot trials Astrazeneca suggest including:	Thank you for your comment – subgroups

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		If evidence allows, results by eligibility to receive cisplatin-based chemotherapy will be considered. Considering the comparators included in the draft scope to show consistency with previous appraisal this section could also include: If evidence allows, results by level of PD-L1 expression will be considered	have been added to the scope.
Comparators	Action Bladder Cancer UK	Consideration should be given whether the named comparators would be available for all patients in this MIBC group, and are available through their NHS Trust. Muscle-invasive bladder cancer is an aggressive disease in which radical cystectomy with pelvic lymph-node dissection remains the standard curative-intent approach and current standard of care. Neoadjuvant cisplatin-based chemotherapy improves survival and is the preferred perioperative strategy. However, it is important to note that nearly 50% of patients are cisplatin-ineligible, (older, frailer, and with greater comorbidities), and therefore currently without effective neoadjuvant options. These patients often then proceed directly to surgery (RC) and demonstrate inferior outcomes.	Thank you for your comment. The comparators have been kept broad at this stage.
	MSD UK	NICE guideline NG2 (3) recommends cisplatin-based neoadjuvant chemotherapy followed by radical cystectomy (RC) plus pelvic lymph node dissection (PLND) for cisplatin-eligible patients with muscle-invasive bladder cancer (MIBC). Patients who are cisplatin-ineligible, or who decline cisplatin, receive RC + PLND alone with no active treatment. For patients at high risk of recurrence after RC + PLND (based on post-surgical pathology) whose tumours express PD-L1 ≥1%, adjuvant nivolumab is recommended in NICE TA817 (4). This is, however, distinct from the perioperative treatment pathway.	Thank you for your comments. The comparators have been amended but kept broad at this stage. The company can include the rationale for relevant comparators in the company

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		Relevant comparators Cisplatin-eligible patients: MSD agrees that cisplatin-based neoadjuvant chemotherapy is the appropriate comparator for this appraisal in cisplatin-eligible patients. Cisplatin-based neoadjuvant chemotherapy is the standard recommended treatment for patients with MIBC who are fit enough to receive it, as per NICE NG2.Durvalumab in combination with gemcitabine and cisplatin for neoadjuvant treatment followed by durvalumab monotherapy as adjuvant treatment (hereafter, 'perioperative durvalumab') in MIBC, has recently been recommended by NICE (5) for cisplatin-eligible MIBC patients. The draft scope currently describes adjuvant durvalumab as being given in combination with gemcitabine and cisplatin, which is incorrect. In the adjuvant setting, durvalumab is given as monotherapy; MSD therefore suggests amending the scope accordingly. MSD agrees that perioperative durvalumab is an appropriate comparator for cisplatin-eligible patients. Nevertheless, there is uncertainty regarding the future uptake of perioperative durvalumab. MSD therefore considers cisplatin-based chemotherapy to be the established standard of care and the primary comparator for decision-making. Cisplatin-ineligible patients: Patients who are ineligible for cisplatin receive no active treatment before RC + PLND. Treatments considered not to be relevant comparators MSD suggests removing adjuvant nivolumab, adjuvant cisplatin-based chemotherapy and best supportive care (BSC) from the comparator list for this appraisal. MSD considers adjuvant nivolumab and adjuvant cisplatin-based chemotherapy regimens inappropriate comparators for this appraisal because of the fundamental difference in timing of decision-making for perioperative or	submission. The appraisal committee will consider which treatments are used in clinical practice for all patients within the marketing authorisation.

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		neoadjuvant approaches versus adjuvant approaches. Perioperative or neoadjuvant treatment decisions are made proactively before surgery, whereas adjuvant treatment decisions are made reactively after surgery, based on post-operative assessments. Therefore, an adjuvant treatment cannot be pre-selected as an alternative to a perioperative regimen and, as a result, clinical settings and populations are not directly comparable. Further details are outlined below. Adjuvant nivolumab in people with PD-L1 ≥1% high risk patients Firstly, adjuvant nivolumab and perioperative pembrolizumab plus EV (P+EV) occupy different positions in the treatment pathway and address distinct MIBC populations; they are not therapeutic alternatives and therefore should not be directly compared. • Patients eligible for adjuvant nivolumab represent only a small subset of the patients who would be treated within the current treatment pathway. As described in TA817 (4) and the CheckMate-274 (6) trial, adjuvant nivolumab is indicated for patients at high risk of recurrence following RC (defined by post-surgical tumour stage as any pT2–pT4a or pT0/x–pT4a/N+ in those who received neoadjuvant cisplatin, and any pT3–pT4a or pT0/x–pT4a/N+ in those who did not receive neoadjuvant cisplatin and are ineligible for or decline adjuvant cisplatin) whose tumours express PD-L1 at ≥1%, and only when adjuvant platinum-based chemotherapy is unsuitable. • Nivolumab as adjuvant therapy represents a reactive or salvage option in response to a high post-surgical risk of recurrence, whereas neoadjuvant and perioperative strategies are proactive approaches initiated before surgery, selected based on pre-surgical cisplatin-eligibility status. Under NICE guidance for TA817 (4), adjuvant	

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		nivolumab cannot be integrated into a predefined neoadjuvant or perioperative treatment pathway, because decisions regarding its use depend on post-surgical pathology assessment of recurrence risk and PD-L1 status. A clinician cannot decide to treat with adjuvant nivolumab instead of perioperative P+EV given that eligibility for nivolumab cannot be determined before surgery (i.e. at the point where the decision to treat with P+EV is made). • Adjuvant nivolumab has not been compared against the current standard of care — neoadjuvant cisplatin-based chemotherapy followed by RC — in MIBC. In CheckMate-274 (6) (and TA817) (4), the comparator was adjuvant placebo, not active neoadjuvant therapy. Secondly, the KEYNOTE-905 (2) and KEYNOTE-B15 (1) trials allowed adjuvant nivolumab to be offered to patients in the control arms who were high-risk based on post-surgical findings; therefore, the KEYNOTE-905 (2) and KEYNOTE-B15 (1) trial comparators already reflect the use of adjuvant nivolumab in clinical practice. • The KEYNOTE-905 (2) and KEYNOTE-B15 (1) trial protocols were amended to allow adjuvant nivolumab as a subsequent treatment option in the control arm for patients for whom it was deemed clinically appropriate. • Results from KEYNOTE-905 (2) and KEYNOTE-B15 (1) show that the proportion of control arm patients receiving adjuvant nivolumab (5–10%), is consistent with UK clinical practice as reflected in the final draft guidance for perioperative durvalumab (ID6168) (5). Clinical experts consulted by MSD considered it appropriate to evaluate adjuvant nivolumab as a subsequent treatment option (that is, to	

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		neoadjuvant chemotherapy and RC+PLND) in line with the protocol amendments, current standard of care options, and its place in the treatment decision pathway. • Consequently, adjuvant nivolumab is already accounted for within the trial data for the relevant comparators for both the cisplatin-eligible (neoadjuvant cisplatin-based chemotherapy followed by RC + PLND) and cisplatin-ineligible (RC + PLND alone) subgroups. This allows a more representative and pragmatic assessment of the comparative efficacy and cost-effectiveness of perioperative P+EV versus current standard of care than considering adjuvant nivolumab a standalone comparator. Adjuvant cisplatin-based chemotherapy Cisplatin-based chemotherapy as adjuvant treatment is not considered a relevant comparator for this appraisal for the following reasons: • Adjuvant cisplatin is not standard of care in the UK. As noted in TA817, most cisplatin-eligible patients receive neoadjuvant cisplatin and are therefore not candidates for additional cisplatin post-surgery. • For patients who did not receive neoadjuvant therapy, evidence supporting adjuvant cisplatin-based chemotherapy is limited according to ESMO Guidelines (7) and therefore it is not recommended for use in clinical practice. Neoadjuvant chemotherapy is the preferred treatment option. • All patients in the control arm of KEYNOTE-B15 (1) trial will have received neoadjuvant chemotherapy and will therefore be ineligible for adjuvant cisplatin-based chemotherapy, which reflects clinical practice in the UK. Patients in the KEYNOTE-905 (2) trial were cisplatin-	

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		ineligible or decliners, therefore cannot receive cisplatin-based chemotherapy in any setting. Best supportive care (BSC) BSC is not considered a relevant comparator in this curative, RC-based pathway. BSC typically refers to care given in the palliative setting for symptom management when treatment is not an option, and therefore it is not relevant in the curative setting. In the cisplatin-eligible subgroup, patients would in practice be offered cisplatin-based therapy and thus receive active treatment rather than supportive care alone. Patients who are ineligible for (or decline) cisplatin still undergo RC but receive no systemic neoadjuvant (or adjuvant) therapy; therefore, in cisplatin-ineligible patients it would be more appropriate to refer to 'no active treatment' in the neoadjuvant and adjuvant settings. Proposed amendment to the comparator list MSD proposes amending the comparators list to reflect the available treatment regimens at the point of decision-making within the perioperative treatment pathway in current standard of care in England, as suggested below: Established clinical management without perioperative pembrolizumab with enfortumab vedotin, including: Neoadjuvant (before surgery) treatment: • Cisplatin-based chemotherapy (in cisplatin-eligible patients) • Durvalumab with gemcitabine and cisplatin (in cisplatin-eligible patients) • No active treatment (in cisplatin-ineligible patients) Adjuvant (after surgery) treatment: • Durvalumab monotherapy (in cisplatin-eligible patients)	

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		• No active treatment (in cisplatin-ineligible patients)	
	Fight Bladder Cancer	Yes	Thank you for your comment.
	British Uro-Oncology Group	Appropriate	Thank you for your comment.
	Astellas	There is a factual inaccuracy relating to the ongoing durvalumab appraisal – in the adjuvant setting, durvalumab is given as monotherapy (rather than durvalumab in combination with gemcitabine and cisplatin as is currently listed).	Thank you for your comment. The comparators have been updated.
	AstraZeneca	Durvalumab with gemcitabine and cisplatin before surgery (neoadjuvant) then alone after surgery (adjuvant) Final Draft Guidance has been published the 10th of February 2026, please remove 'subject to NICE evaluation'. As included in ID6168 Company Submission, UK-based clinical experts consider perioperative durvalumab in combination with gemcitabine and cisplatin to be the new standard of care for patients with resectable MIBC who are eligible to receive cisplatin-based chemotherapy. As Durvalumab is only given as combination with gemcitabine and cisplatin in the neoadjuvant phase, AstraZeneca suggest amending the text to include a third category as: For perioperative treatment:	Thank you for your comment. The comparators have been updated.

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		• Durvalumab with gemcitabine and cisplatin before surgery then alone after surgery for patients who are eligible to receive cisplatin-based chemotherapy Or amending the mention to durvalumab as adjuvant treatment to: For adjuvant treatment: Durvalumab monotherapy for patients who are eligible to receive cisplatin-based chemotherapy	
Outcomes	Action Bladder Cancer UK	They are appropriate. However, it is key that the impact on patients being less likely to experience cancer recurrence, disease progression, not undergoing surgery, or death with EVP before and after surgery as compared with current treatment standard is given due weight.	Thank you for your comment.
	MSD UK	MSD considers that the outcome measures listed are appropriate.	Comment noted.
	Fight Bladder Cancer	Yes	Comment noted.
	British Uro-Oncology Group	Appropriate	Comment noted.
Equality	Action Bladder Cancer UK	See note re inequality of women being diagnosed at a later stage than men.	Thank you for your comment. The committee will consider equality issues

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		Equality of access – would all patients be able to access new treatments – in particular rural areas, smaller hospitals etc.	throughout the evaluation.
	MSD UK	• Equality and access: People ineligible for cisplatin (e.g., due to renal impairment, ototoxicity risk, frailty) have fewer effective neoadjuvant options; ensuring the scope clearly recognises a cystectomy alone comparator (with no active treatment) for this subgroup avoids disadvantaging them in the evaluation. • Protected characteristics: Older adults and people with comorbidities (prevalent in MIBC) may be disproportionately affected by cisplatin ineligibility. • Variability in treatment options across the country: some patients living in remote or rural areas must travel long distances for specialist care to larger/higher-capacity centres. Travel may discourage patients from accessing care. If patients are treated in larger centres travel burden may delay or complicate treatment initiation.	Thank you for your comment. The committee will consider equality issues throughout the evaluation.
	British Uro-Oncology Group	Appropriate	Comment noted.
	AstraZeneca	This section has not been included in the draft scope remitted.	Thank you for your comment. The committee will consider equality issues throughout the evaluation.
Other considerations	Action Bladder Cancer UK	There has a lack of new treatments available for bladder cancer – a common cancer with poor outcomes and high recurrence rates. It is important that this	Thank you for your comments. This

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		new treatment is viewed within that context. There is concern amongst patients, patient groups and clinicians about the slowness to approve new immunotherapies for use in treating bladder cancer in the UK, particularly in the context of paucity of other effective treatments available. There is an acute need for effective new treatments and a significant unmet need for treatment options for this patient group. EVP has already been approved for use in metastatic bladder cancer, allowing confidence and experience to build in the relevant clinical cohort. It is also worth noting that Pembrolizumab has been in use for some time, has demonstrated effective use, and clinicians have become familiar with use and management. Widening use of this exciting new treatment to those patients with muscle invasive disease would be building on this clinical experience to reach a much wider group of patients who currently experience acute unmet needs for treatment options. As noted in the comparator section above, c50% of MIBC patients are cisplatin-ineligible, and without effective neoadjuvant options. Enfortumab vedotin has already demonstrated robust effectiveness in advanced or metastatic bladder cancer, irrespective of cisplatin eligibility. Bladder cancer is one of the most expensive cancers to treat. Within the economic analysis discussions, patients feel it is imperative that due consideration and weight is given not just to the cost of this new treatment, but to the high on-going cost of continued and unsuccessful treatment for those with MIBC, and to the current poor outcomes faced by many patients.	evaluation has been scheduled into the Technology Appraisals work programme. The committee will consider all costs of the technology and comparators within the perspective of the NHS and personal social services.

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		The draft Scope refers to Related NICE guidelines: Bladder cancer: diagnosis and management (2015) NICE guideline NG2. It is of some importance to note that this Guideline is now 11 years since publication in February 2015 (and only reviewed evidence which was available to late 2014). The Guideline does not adequately cover the introduction, evidence of efficacy and availability of new treatments for bladder cancer, is an imperfect clinical guide to management and treatment of bladder cancer, and does not reflect current treatment options.	
	British Uro-Oncology Group	See above re consideration of neoadjuvant and adjuvant therapies separately from their subsequent/prior definitive therapies.	Thank you for your comments. No changes to scope needed.
Questions for consultation	MSD UK	**Where do you consider enfortumab vedotin with pembrolizumab will fit into the existing care pathway for muscle-invasive bladder cancer?** MSD expects that the combination of pembrolizumab with enfortumab vedotin will be used in line with its expected marketing authorisation in perioperative settings: [redacted] **Please select from the following, will enfortumab vedotin with pembrolizumab be:** C. Prescribed in secondary care with routine follow-up in secondary care: Pembrolizumab with enfortumab vedotin will be prescribed and monitored in specialist urology/oncology centres with perioperative MDT oversight. **For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.** The setting for prescribing and routine follow-up for comparators and subsequent treatments does not differ from the intervention.	Thank you for your comments. The committee will consider pembrolizumab with enfortumab vedotin within its marketing authorisation. No changes to the scope required.

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		Would enfortumab vedotin with pembrolizumab be a candidate for managed access? MSD consider that there is sufficient evidence already available to enable a recommendation for routine commissioning at this stage. The submission to NICE will be made based on data from an interim analysis of KEYNOTE-905 and KEYNOTE-B15 trials. Further follow-up data will become available in the future, which may mean it is appropriate to consider this technology as a managed access candidate to enable patient access if a baseline recommendation is not feasible. **Do you consider that the use of enfortumab vedotin with pembrolizumab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation? Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.** MSD consider that the use of pembrolizumab in combination with enfortumab vedotin will include all potential substantial health-related benefits in the QALY calculation.	
	British Uro-Oncology Group	Where do you consider enfortumab vedotin with pembrolizumab will fit into the existing care pathway for muscle-invase bladder cancer? Prescribed in secondary care with routine follow-up in secondary care	Thank you for your comment. No changes to the scope required.
Additional comments on the draft scope	MSD UK	MSD suggests adding pembrolizumab details under the technology section, currently it includes information on enfortumab vedotin only.	Thank you for your comment. The technology section of

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			the scope has been updated.

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

None