

National Institute for Health and Care Excellence

Health Technology Evaluation

Teclistamab for treating relapsed or refractory multiple myeloma after 3 treatments (Review of TA869) [ID6333]

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	Janssen-Cilag Limited	No comments.	Thank you. No action is needed.
	GlaxoSmithKline	The topic and proposed evaluation route are appropriate.	Thank you for your comment. No action is needed.
	Myeloma UK	No comments.	Thank you. No action is needed.
	Royal College of Pathologists	Appropriate evaluation and proposed route	Thank you for your comment. No action is needed.

Section	Stakeholder	Comments [sic]	Action
	pharma&	We believe it is appropriate that this topic is referred to NICE for appraisal.	Thank you for your comment. No action is needed.
	Takeda	The topic and evaluation route are appropriate.	Thank you for your comment. No action is needed.
Wording	Janssen-Cilag Limited	The wording of the remit is appropriate.	Thank you for your comment. No action is needed.
	GlaxoSmithKline	The wording of the remit reflects the issue(s) of clinical and cost effectiveness about this technology that NICE should consider.	Thank you for your comment. No action is needed.
	Myeloma UK	Myeloma UK considers the remit to reflect the issues of clinical and cost effectiveness.	Thank you for your comment. No action is needed.
	Royal College of Pathologists	Yes	Thank you. No action is needed.
	pharma&	No comment	Thank you. No action is needed.
	Takeda	No comment.	Thank you.

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			No action is needed.
Timing Issues	Janssen-Cilag Limited	<p>Patients who have received the main 3 classes of multiple myeloma (MM) therapies continue to face a dearth of effective and quality of life-preserving treatment options in the UK.</p> <p>The expected median survival for a patient with relapsed and refractory multiple myeloma (RRMM) who has been exposed to anti-CD38 monoclonal antibody (CD38 mAb), a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD) and treated is < 18 months (1).</p> <p>Patients and the clinical team in charge of their care are still waiting for new treatment options due to unprecedented access setbacks to innovation with numerous HTA suspended/ terminated (e.g., TA889, ID1442) or with negative outcomes (e.g. ID2701) in this treatment setting, all in 2023 alone.</p> <p>As such, given the significant unmet need in this patient population, access to effective treatments such as teclistamab should be considered a priority.</p> <p>1 References: Mateos, MV., Weisel, K., De Stefano, V. et al. LocoMMotion: a prospective, non-interventional, multinational study of real-life current standards of care in patients with relapsed and/or refractory multiple myeloma. Leukemia 2022; 36, 1371–1376</p>	<p>Thank you for your comments. The topic has been scheduled into NICE program.</p> <p>No action is needed.</p>
	GlaxoSmithKline	The timing of this appraisal is appropriate considering the high unmet need for patients in the 4L+ triple class exposed setting.	<p>Thank you for your comment.</p> <p>No action is needed.</p>
	Myeloma UK	No comments.	<p>Thank you.</p> <p>No action is needed.</p>
	Royal College of Pathologists	It would be good if this evaluation could be available by Q1 2024 if at all possible	<p>Thank you for your comment. The topic has</p>

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			been scheduled into NICE program. No action is needed.
	pharma&	No comment	Thank you. No action is needed.
	Takeda	No comment.	Thank you. No action is needed.
Additional comments on the draft remit	Janssen-Cilag Limited	No comment	Thank you. No action is needed.
	GlaxoSmithKline	NA	No action is needed.
	Royal College of Pathologists	N/A	No action is needed.
	pharma&	None	Thank you. No action is needed.
	Takeda	None.	Thank you. No action is needed.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Janssen-Cilag Limited	No additional comments	Thank you. No action is needed.
	GlaxoSmithKline	The background information is considered to be accurate and complete.	Thank you for your comment. No action is needed.
	Myeloma UK	We consider this information to be sufficient and accurate.	Thank you for your comment. No action is needed.
	Royal College of Pathologists	Satisfactory	Thank you for your comment. No action is needed.
	pharma&	No comment	Thank you. No action is needed.
	Takeda	No comment.	Thank you. No action is needed.
Population	Janssen-Cilag Limited	To align with the licensed wording, Janssen suggest that the population is described as: 'adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent,	Thank you for your comment. The population definition was amended

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		a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. '	in line with marketing authorisation.
	GlaxoSmithKline	As per the marketing authorisation, teclistamab is indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. In line with the SmPC, confirmed relapse on the last therapy should be considered when defining the population in the final scope.	Thank you for your comment. The population definition was amended in line with marketing authorisation.
	Myeloma UK	<p>We consider the population to be appropriately defined.</p> <p>We welcome that it has not been restricted and is in line with the marketing authorisation.</p> <p>Despite approvals for treating myeloma in recent years given the heterogeneity of the disease an unmet need remains and there is a need for flexibility at each stage of the pathway.</p> <p>It is common in myeloma appraisals that final company submissions are narrower than full marketing authorisation.</p> <p>If the company seeks to pursue NICE approval for a narrower patient population than the final marketing authorisation it is vital that this reflects unmet need, current and likely future gaps in the pathway, and is not just driven by commercial considerations.</p>	Thank you for your comments. Please note, the population definition was amended in line with marketing authorisation.
	Royal College of Pathologists	Yes	Thank you for your comment. Please note, the population definition

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			was amended in line with marketing authorisation.
	pharma&	We believe the population is defined appropriately.	Thank you for your comments. Please note, the population definition was amended in line with marketing authorisation.
	Takeda	Yes.	Thank you for your comments. Please note, the population definition was amended in line with marketing authorisation.
Subgroups	Janssen-Cilag Limited	<p>The pivotal clinical trial for this appraisal, MajesTEC-1, included the following cohorts:</p> <ul style="list-style-type: none"> • patients with no prior BCMA-directed treatment and • patients who have previously received BCMA-directed treatment. <p>As BCMA-directed treatment is not currently available in the UK, the generalisability of results of patients who previously received BCMA-directed treatment are not generalisable to the UK. Clinical effectiveness will be examined separately for these cohorts.</p>	Thank you for your comment. No action is needed.

Section	Consultee/ Commentator	Comments [sic]	Action
		Given the high unmet need and poor outcomes observed in later lines of multiple myeloma treatment, Janssen consider that teclistamab should be made available to all eligible patients, such that there are no subgroups which should be considered separately.	
	GlaxoSmithKline	No subgroups suggested.	Thank you for your comment. No action is needed.
	Myeloma UK	No comments.	Thank you. No action is needed.
	Royal College of Pathologists	No	Thank you. No action is needed.
	pharma&	No comment	Thank you. No action is needed.
	Takeda	No subgroups suggested.	Thank you for your comment. No action is needed.
Comparators	Janssen-Cilag Limited	There is an urgent need for new treatments with novel mechanisms of action to improve outcomes for patients with MM. There is currently no single established standard of care for patients who have received at least three prior therapies, including an immunomodulatory agent, a PI, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy ¹ .	Thank you for your comments. Belantamab madofotin has been removed because MHRA is currently assessing the

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		<p>In the absence of an established standard of care, pomalidomide plus low-dose dexamethasone (TA427) is a relevant comparator for teclistamab in patients who have received 3 prior therapies, including a PI, an IMiD, and a CD38 mAb. In addition, pomalidomide plus low-dose dexamethasone has been accepted as the only relevant comparator after 3 previous lines of treatment in prior NICE multiple myeloma appraisals (TA783, TA658). This was echoed in a UK registry publication suggesting that pomalidomide and dexamethasone is the preferred option, with only a minority receiving panobinostat plus bortezomib and dexamethasone².</p> <p>Cyclophosphamide plus dexamethasone or an alternative alkylating chemotherapy is not standard of care for patients at the 4th line setting, and as such is not a relevant comparator. Clinical insights received from Janssen indicate that this chemotherapy combination would either be used earlier in the UK treatment pathway, and typically used in combination with a PI, such as bortezomib. Or alternatively, clinical insights suggests that this combination is used as a salvage option due to a lack of effective treatment options.</p> <p>Lenalidomide plus dexamethasone (TA171) is not a relevant comparator because patients would have received it earlier in therapy as first- (TA587) or second- (TA586) line treatment in this setting. This is further supported by clinical experts in TA505, as well as in comments for the scoping consultation of ID4026, stated that lenalidomide plus dexamethasone is mainly used after 2 prior therapies, and that it can be used for people who had 3 previous therapies, provided that they have not had lenalidomide before. Due to the disease pathophysiology, recycling of existing therapies in RRMM has limited efficacy as patients are re-exposed to treatments or classes of agents that they have previously developed resistance to.³</p>	<p>annual renewal of the GB marketing authorisation. NICE is therefore withdrawing the Final Draft Guidance for this topic (ID2701) and the appraisal is paused.</p> <p>Other comparators remain unchanged. The comparators listed in the scope aim to be inclusive. Some comparators are included with the caveat that this is subject to the outcome of the NICE evaluation. Stakeholders can provide justification around the most appropriate comparators and the committee will consider this during the appraisal.</p>

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		<p>As such, given this combination would most likely be used earlier in the pathway, the re-use in this setting would be limited by previous exposure at earlier lines in the pathway.</p> <p>Daratumumab monotherapy (TA783) is recommended in patients with relapsed or refractory multiple myeloma after 3 prior therapies. Patients eligible for teclistamab, however, will have received daratumumab in earlier lines of therapy (for example, daratumumab in combination with bortezomib and dexamethasone TA897, or daratumumab in combination with lenalidomide and dexamethasone, ID3843). As patients are not routinely re-challenged with daratumumab in later lines of therapy, daratumumab monotherapy is not a relevant comparator for patients who have already been exposed to the CD38 mAB, in this setting.</p> <p>Due to ongoing toxicity concerns, panobinostat plus bortezomib and dexamethasone (TA380) is no longer a relevant comparator for this setting in the UK, as confirmed through committee conclusions in TA658 and TA783. Clinical experts in TA658 and TA783 confirmed that panobinostat plus bortezomib and dexamethasone is very rarely used after 3 previous lines of treatment because of toxicity and perceived poor clinical efficacy. Furthermore, NICE have removed panobinostat plus bortezomib and dexamethasone as a relevant comparator in 4th line (ID4067), due to the Committee's conclusion in TA658, as well as comments received during the consultation.</p> <p>Belantamab mafodotin is not a relevant comparator as it is not currently considered a standard treatment currently used in the NHS. Furthermore, the CHMP has recommended not renewing the conditional marketing authorisation for belantamab mafodotin. The MHRA will make the decision on whether the licence is not renewed within the UK. Until NICE have received</p>	

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		<p>the MHRA's decision, the NICE appraisal for belantamab madofotin (ID2701) has been paused.</p> <p>Janssen consider that ixazomib plus lenalidomide and dexamethasone (TA870) is not a relevant comparator. As this combination contains lenalidomide, patients who previously received lenalidomide are not routinely re-challenged in later lines of therapy. Furthermore, ixazomib plus lenalidomide and dexamethasone is mostly used in the 3rd line setting, based on expert clinical opinion.</p> <p>Isatuximab with pomalidomide and dexamethasone is not a relevant comparator in this setting. Patients who are eligible for isatuximab with pomalidomide and dexamethasone are those who are not previously refractory to a CD38 mAb, which represent a different cohort of patients to those eligible for teclistamab.</p> <p>In addition, isatuximab with pomalidomide and dexamethasone is not currently routinely commissioned in the UK and so should not be considered a relevant comparator at this time. Despite the ongoing CDF review and potential for a positive outcome, NICE removed isatuximab with pomalidomide and dexamethasone from the final scope of ID4026, as it would not be in routine use by the time of the submission.</p> <p>Elranatamab is not a relevant comparator for teclisitamab in this setting at this time, as it is pending NICE guidance. Therefore, elranatamab is not currently considered a standard treatment currently used in the NHS and will not be in routine use by the time of the submission.</p> <p>References:</p>	

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		<p>1) Mateos, MV., Weisel, K., De Stefano, V. et al. LocoMMotion: a prospective, non-interventional, multinational study of real-life current standards of care in patients with relapsed and/or refractory multiple myeloma. <i>Leukemia</i> 2022; 36, 1371–1376</p> <p>2) Elsada A, Zalin-Miller A, Knott C, Caravotas. A registry study of relapsed or refractory multiple myeloma pre-exposed to three or more prior therapies including a proteasome inhibitor, an immunomodulatory agent and CD38-targeted monoclonal antibody therapy in England. <i>eJHaem</i> 2021:https://doi.org/10.1002/jha2.214</p> <p>3) Kumar SK, Lee JH, Lahuerta JJ, Morgan G, Richardson PG, Crowley J, et al. Risk of progression and survival in multiple myeloma relapsing after therapy with IMiDs and bortezomib: A multicenter international myeloma working group study. <i>Leukemia</i>. 2012 Jan;26(1):149–57</p>	
	GlaxoSmithKline	<p>The comparators listed are considered to be the standard treatments currently used in the NHS with which the technology should be compared, except for cyclophosphamide plus dexamethasone. Cyclophosphamide plus dexamethasone is palliation rather than an active treatment approach. The intention of palliation is to provide the patient with a symptom-controlled death, making them as comfortable as possible at the end of their journey with their disease, which is different to an active treatment where the intention is to provide the patient with a period of progression-free survival. Health technology assessment requires relevant alternatives to be chosen as comparators and palliation is not a relevant alternative for patients who are still fit enough to receive an active treatment.</p>	<p>Thank you for your comments.</p> <p>The comparators listed in the scope aim to be inclusive. Stakeholders can provide justification around the most appropriate comparators and the committee will consider this during the appraisal.</p> <p>Please note, belantamab mafodotin has been removed to</p>

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			reflect consultation comments.
	Myeloma UK	<p>We agree that these are treatments available to this patient population.</p> <p>However, Myeloma UK believes that pomalidomide and dexamethasone should be the current standard comparator.</p> <p>In current clinical practice it is our understanding that patients, after at least 3 prior therapies, will receive:</p> <ul style="list-style-type: none"> • Pomalidomide plus low-dose dexamethasone • Cyclophosphamide and dexamethasone OR alternative alkylating chemotherapy and corticosteroid (only used when pomalidomide plus low-dose dexamethasone is not suitable) • Daratumumab monotherapy (use limited by previous exposure to daratumumab at earlier lines) • Ixazomib plus lenalidomide and dexamethasone (use may be limited by previous exposure to lenalidomide at earlier lines) • Isatuximab plus pomalidomide and dexamethasone (use limited by previous exposure to daratumumab at earlier lines and is subject to NICE evaluation) • Clinical trial • Compassionate use / Early access scheme <p>The combination of panobinostat plus bortezomib and dexamethasone is not widely used in clinical practice and should not be used as a comparator in this NICE appraisal.</p>	<p>Thank you for your comments.</p> <p>As suggested, belantamab mafodotin has been removed. Other comparators remain unchanged. The comparators listed in the scope aim to be inclusive. Stakeholders can provide justification around the most appropriate comparators and the committee will consider this during the appraisal.</p>

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		The combination lenalidomide plus dexamethasone is not widely used at fourth line and beyond as majority of patients will have received lenalidomide at previous lines of treatment.	
	Royal College of Pathologists	Yes. Yes.	Thank you for your comments. Please note, belantamab mafodotin has been removed to reflect consultation comments.
	pharma&	We believe that all relevant comparators have been included.	Thank you for your comments. Please note, belantamab mafodotin has been removed to reflect consultation comments.
	Takeda	In general, Yes. We note that isatuximab with pomalidomide and dexamethasone is currently within the CDF.	Thank you for your comments. Isatuximab with pomalidomide and dexamethasone is included with the caveat that this is subject to the

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			outcome of the NICE evaluation. Please note, belantamab mafodotin has been removed to reflect consultation comments.
Outcomes	Janssen-Cilag Limited	The outcomes listed are appropriate	Thank you for your comment. No action is needed.
	GlaxoSmithKline	The outcomes listed are appropriate.	Thank you for your comment. No action is needed.
	Myeloma UK	Yes.	Thank you for your comment. No action is needed.
	Royal College of Pathologists	Yes. Yes.	Thank you for your comments. No action is needed.
	pharma&	No comment	Thank you. No action is needed.

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	Takeda	Yes and yes.	Thank you for your comments. No action is needed.
Equality	Janssen-Cilag Limited	No equality issues have been identified.	Thank you for your comment. No action is needed.
	GlaxoSmithKline	No equality issues identified.	Thank you for your comment. No action is needed.
	Myeloma UK	No comments.	Thank you. No action is needed.
	Royal College of Pathologists	No changes required.	Thank you for your comment. No action is needed.
	pharma&	No comment	Thank you. No action is needed.
	Takeda	No equality issues identified.	Thank you for your comment. No action is needed.

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Other considerations	Janssen-Cilag Limited	No comments.	Thank you. No action is needed.
	GlaxoSmithKline	<p>The high rates of hypogammaglobulinemia with BCMA-directed bites and consequent infections, support universal use of immunoglobulin (IG) replacement therapy.¹ The service impact arising from this should be considered. In the UK, the national shortage of intravenous IG should also be considered as an access barrier in this context.²</p> <p>References: ¹ Garfall, A. L., E. A. Stadtmauer. Understanding Infection Risk with Anti-BCMA Bispecific Antibodies. Blood Cancer Discovery: OF1-OF3. In 2023. ² Immunodeficiency [Internet]. 2020 [cited 2023 Oct 23]. Available from: http://www.immunodeficiencyuk.org/</p>	<p>Thank you for your comment.</p> <p>The committee will review all relevant evidence.</p> <p>No action is needed.</p>
	Royal College of Pathologists	Need to consider the additional economic impact of teclistamab, for example the cost of the additional bed days, funding of tocilizumab and immunoglobulin replacement	<p>Thank you for your comment.</p> <p>The committee will review all relevant evidence.</p> <p>No action is needed.</p>
	pharma&	None	<p>Thank you.</p> <p>No action is needed.</p>
	Takeda	No comments	<p>Thank you.</p> <p>No action is needed.</p>

Section	Consultee/ Commentator	Comments [sic]	Action
Questions for consultation	Janssen-Cilag Limited	<p>What treatments are established clinical practice in the NHS for people with relapsed or refractory multiple myeloma after 3 therapies?</p> <p>As above, there is currently no single established standard of care for patients who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody. In the absence of an established standard of care, Janssen propose that pomalidomide and dexamethasone is a relevant comparator, consistent with committee conclusions in TA889 and TA658. For further details, please see comments on comparators above.</p> <p>Where do you consider teclistamab will fit into the existing care pathway for multiple myeloma?</p> <p>Janssen consider that teclistamab, aligned with its marketing authorisation, will fit as an option for patients who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.</p> <p>Are there any subgroups of people in whom teclistamab is expected to be more clinically effective and cost effective or other groups that should be examined separately?</p> <p>Janssen are currently exploring if any subgroups for teclistamab are appropriate and will provide further clarity later in the NICE submission process. However, considering the significant unmet need and unfavourable outcomes observed in advanced stages of multiple myeloma treatment, Janssen advocates for teclistamab's availability to all eligible patients, without the need for separate subgroup considerations</p>	<p>Thank you for your comments.</p> <p>Please note, belantamab mafodotin has been removed from the list of comparators to reflect consultation comments. No further action is needed.</p>

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		<p>Would teclistamab be a candidate for managed access?</p> <p>Janssen are currently [REDACTED] [REDACTED]</p> <p>Teclistamab has the longest reported follow-up to date for a bispecific antibody (Usmani SZ, et al. ASCO 2023. Poster 8034). [REDACTED] [REDACTED]</p> <p>Do you consider that the use of teclistamab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?</p> <p>Janssen consider that teclistamab, as a first-in-class humanised bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager, works in a completely different way to the myeloma drugs routinely commissioned for use in the UK. This off-the-shelf therapy uses innovative science to activate the immune system by binding to the CD3 receptor expressed on the surface of T-cells and to the B-cell maturation antigen (BCMA) expressed on the surface of multiple myeloma cells and some healthy B-lineage cells. The benefit of an additional treatment option for patients at this stage of the disease pathway may not be captured in the QALY framework.</p> <p>A diagnosis of MM also has a substantial psychological impact, with patients living in fear of relapse. Improvements in mental health, reduced anxiety, and enhanced quality of life due to a new treatment option also may not be</p>	

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		<p>fully accounted for in QALY calculations. Additional psychological benefits from teclistamab, such as prolonged remission and reduction in anxiety associated with relapse, are aligned to MM patient preferences and are not explicitly considered in the QALY framework.</p> <p>Most of the clinical management of MM is provided in the outpatient setting; therefore the bulk of care is informal and provided by carers. The use of teclistamab is expected to result in significant carer benefits, such as reduction in burden of care as a direct result of the reduction in the rate of deterioration of the disease. These benefits may not be fully captured in the QALY framework.</p>	
	GlaxoSmithKline	NA	No action is needed.
	Myeloma UK	<p><i>Would teclistamab be a candidate for managed access?</i></p> <p>The clinical trial for this indication is complete therefore we believe that teclistamab would not be a candidate for managed access.</p> <p><i>Do you consider that the use of teclistamab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?</i></p> <p>Myeloma remains incurable and even after successful treatment, almost all patients eventually become resistant to existing treatments. New drugs and treatment approaches are urgently needed to overcome treatment resistance.</p> <p>Teclistamab is a new type of myeloma drug. It works in a completely different way to the myeloma drugs routinely commissioned for use in the UK.</p> <p>As a B cell maturation antigen (BCMA) targeted T-cell engager it would introduce a novel treatment approach into the pathway. As well as giving</p>	<p>Thank you for your comments.</p> <p>No action is needed.</p>

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		<p>refractory patients hope, it also gives patients who may have never experienced complete response or lengthy remissions an opportunity to do so.</p> <p>The response rates for teclistamab are relatively high compared to other treatments for multiply relapsed myeloma patients. Responding well to a treatment has a huge psychological impact on patients and their families.</p> <p>This is a dexamethasone free treatment. Dexamethasone has a significant impact on the daily lives of patients. It causes mood swings, aggression, mania, insomnia and fatigue. This is difficult for patients and their families to live with.</p>	
	Royal College of Pathologists	<p>I agree that teclistamab would fit into the existing pathway for patients with myeloma after at least 3 previous lines of therapy</p> <p>Teclistamab was previously available as a single patient request (pre-approval access) though this has now closed.</p> <p>The primary outcome in MajesTEC-1 remains relevant. There are no ongoing trials using teclistamab as monotherapy in this setting.</p>	<p>Thank you for your comments.</p> <p>No action is needed.</p>
	pharma&	No comment	No action is needed.
	Takeda	<p>What treatments are established clinical practice in the NHS for people with relapsed or refractory multiple myeloma after 3 therapies?</p> <p>As per the comparators listed.</p> <p>Where do you consider teclistamab will fit into the existing care pathway for multiple myeloma?</p> <p>Within its marketing authorisation, for patients who have received at least 3 prior therapies.</p>	<p>Thank you for your comments.</p> <p>Please note, belantamab mafodotin has been removed from the list of comparators to reflect consultation</p>

Section	Consultee/ Commentator	Comments [sic]	Action
		<p>Are there any subgroups of people in whom teclistamab is expected to be more clinically effective and cost effective or other groups that should be examined separately? No comment.</p> <p>Would teclistamab be a candidate for managed access? No comment.</p> <p>Do you consider that the use of teclistamab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation? No.</p> <p>Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits. Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts. No comment.</p> <p>Would it be appropriate to use the cost-comparison methodology for this topic? No comment.</p> <p>Is the new technology likely to be similar in its clinical efficacy and resource use to any of the comparators? As a monotherapy it seems unlikely to be similar in its clinical efficacy.</p>	<p>comments. No further action is needed.</p>

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		<p>Is the primary outcome that was measured in the trial or used to drive the model for the comparator(s) still clinically relevant? No comment.</p> <p>Is there any substantial new evidence for the comparator technology/ies that has not been considered? Are there any important ongoing trials reporting in the next year? No comment.</p>	
Additional comments on the draft scope	Janssen-Cilag Limited	<p>The landscape of multiple myeloma treatments is rapidly evolving and the therapeutic field for the management of the condition is continuously changing. There is an urgent unmet need for truly effective therapies that gain an overall response for the majority of patients and have significant durability of disease control following relapse after prior exposure to a PI, IMiD, and mAb.</p> <p>Current treatment options are limited and suboptimal. Moreover, prognosis and quality of life are poor, with very short overall and progression free survival, highlighting the significant burden of illness and poor survival prospects associated with this late stage in therapy. For patients who have reached the end of their treatment pathway and faced limited life expectancy, the value of having an additional treatment option is hard to assess. This challenge is further intensified by the recent unforeseen setbacks in NICE appraisals in this specific line of treatment.</p> <p>Despite these complexities, the committee now holds a real opportunity to make a profoundly positive impact on a substantial number of myeloma patients/carers/healthcare teams through the approval of this technology.</p>	<p>Thank you for your comments.</p> <p>No action is needed.</p>

Section	Consultee/ Commentator	Comments [sic]	Action
	GlaxoSmithKline	NA	No action is needed.
	Royal College of Pathologists	N/A	No action is needed.
	pharma&	None	Thank you. No action is needed.
	Takeda	None	Thank you. No action is needed.

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

None.