National Institute for Health and Care Excellence

Health Technology Evaluation

Ciltacabtagene autoleucel for treating relapsed and lenalidomide-refractory multiple myeloma after 1 to 3 therapies [GID-TA12518]

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	Johnson & Johnson	The evaluation and proposed evaluation route are appropriate.	Thank you for your comment.
	GlaxoSmithKline	The topic and proposed evaluation route are appropriate.	Thank you for your comment.
Wording	Johnson & Johnson	J&J agree that the current wording of the decision problem remit reflects the marketing authorisation.	Thank you for your comment.
	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.
	Myeloma UK	Myeloma UK considers the remit to reflect the issues of clinical and cost effectiveness.	Thank you for your comment.

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Timing issues	Johnson & Johnson	J&J believe the evaluation of this indication is of urgency to the NHS, reflecting a rapidly evolving multiple myeloma (MM) treatment pathway, a growing population of patients with early relapsed, lenalidomide-refractory disease who have limited effective options, and an increasing need for novel, clinically meaningful therapies earlier in the pathway. MM is a rare haematological cancer accounting for 2% of all new cancer cases in England and is associated with high clinical burden, with patients often presenting with recurring or persistent infection, fatigue and unremitting bone pain.[1,2] Historically, patients with MM would relapse following a period of remission or response. However, more recent treatments have demonstrated the potential for patients to achieve deep and durable responses without subsequent relapse.[3] Emerging novel therapies, such as ciltacabtagene autoleucel (cilta-cel) in CARTITUDE-1 (in heavily pre-treated patients), provides direct evidence of sustained MRD-negative remission without the need for ongoing therapy, supporting the transition of outcomes in patients with MM to potential cure.[4] Organisations such as the International Myeloma Working Group (IMWG) and the International Myeloma Society (IMS) have each proposed a draft definition of functional cure, paving the way for unprecedented outcomes in MM. Lenalidomide is a key backbone of contemporary MM treatment, being widely used in first-line therapy (for both transplant eligible and ineligible patients) and often continued as maintenance therapy until progression to second line.[5] This has led to a growing and increasingly clinically relevant population of patients whose disease is refractory to lenalidomide. This issue is particularly important in relapsed refractory multiple myeloma (RRMM), where recommended treatment options in the NHS become increasingly limited	Thank you for your comments. This topic has been entered into the work schedule.

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		once patients become refractory to lenalidomide as generally, these patients are not re-treated with lenalidomide. As a result, outcomes in this population remain suboptimal. For example, real-world outcomes from a retrospective UK cohort of patients with relapsed MM previously treated with lenalidomide showed that those who became lenalidomide-refractory had significantly shorter median OS compared with those who did not (26.2 months vs not reached; p<0.0001).[6] Evidence from a systematic literature review of clinical trials and real-world studies also demonstrates that in relapsed, lenalidomide-refractory MM, outcomes are poor, with a population-weighted mean median progression-free survival (PFS) of 8.8 months and median overall survival (OS) of 21.7 months in population-matched clinical trial cohorts.[7] These findings highlight a clinical unmet need to improve treatment options for the lenalidomide-refractory population, especially in earlier lines. There is a strong rationale to prioritise access to therapies that can meaningfully improve the durability of response in patients with relapsed, lenalidomide-refractory MM, while also minimising treatment-related toxicity. Recently approved therapies such as, belantamab mafodotin in combination with bortezomib and dexamethasone (BVd; TA1149)[8] and pomalidomide and dexamethasone (BPd; TA1133),[9] offer survival benefits in the treatment of RRMM, including in lenalidomide-refractory populations, in the second line setting. However, these regimens are associated with severe ocular toxicities, which can adversely impact patient quality of life as discussed by the EAG in the final draft guidance for BVd (TA1149) and BPd (TA1133).[8-11] As well as experiencing these toxicities, patients often require clinical management until resolution. Data from the DREAMM-7 and DREAMM-8 studies show that, among patients experiencing ≥ 2 ocular events, the median duration of first keratopathy and visual acuity (KVA) events was 106 days and 80.5 days,	

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		respectively.[10,11] This duration of toxicity is likely to necessitate ongoing monitoring, supportive care and potential treatment modifications,[12] thus contributing to additional healthcare resource use and burden on the NHS services. Additionally, many regimens in the RRMM pathway include dexamethasone. While effective, dexamethasone is associated with substantial physical and psychological side effects including mood disturbances, insomnia, muscle weakness and osteoporosis. Given the underlying complications of MM, particularly bone disease, prolonged steroid use may further exacerbate musculoskeletal symptoms and contribute to additional treatment burden.[13] This evaluation addresses a clinically relevant and pressing gap in NHS practice by targeting patients across different lines of the disease course, where outcomes with existing regimens are suboptimal, long-term disease control is difficult to sustain and severe treatment related adverse events persist. There is a clear need for novel therapies such as cilta-cel that can deliver deep and durable responses, with evidence suggesting the curative potential for some patients.[4] Furthermore, cilta-cel offers the potential for prolonged treatment-free remission following a single administration, while also avoiding ongoing dexamethasone exposure and its associated toxicities. Therefore, access to effective treatments such as cilta-cel should be considered a priority. <u>References:</u> 1. Cancer Research UK. Myeloma Statistics 2017, 2017.	

Section	Stakeholder	Comments [sic]	Action
		2. Weber DM, Chen C, Niesvizky R, et al. Lenalidomide plus dexamethasone for relapsed multiple myeloma in North America. N Engl J Med 2007;357:2133-42. 3. Sonneveld P, et al. Oral Presentation. 6th European Myeloma Network (EMN) meeting. April 10-12, 2025 4. Jagannath S, Martin TG, Lin Y, et al. Long-Term (≥5-Year) Remission and Survival After Treatment With Ciltacabtagene Autoleucel in CARTITUDE-1 Patients With Relapsed/Refractory Multiple Myeloma. J Clin Oncol. 2025 Sep;43(25):2766-2771. doi: 10.1200/JCO-25-00760. Epub 2025 Jun 3. PMID: 40459151; PMCID: PMC12393059. 5. Mikhael J, Ismaila N, Cheung MC, et al. Treatment of Multiple Myeloma: ASCO and CCO Joint Clinical Practice Guideline. J Clin Oncol 2019;37:1228-1263 6. Lecat CSY, Taube JB, Wilson W, et al. Defining Unmet Need Following Lenalidomide Refractoriness: Real-World Evidence of Outcomes in Patients With Multiple Myeloma. Front Oncol. 2021 Jul 21;11:703233. doi: 10.3389/fonc.2021.703233. PMID: 34367987; PMCID: PMC8335564. 7. Hartley-Brown MA, Weisel K, Bitetti J, Carter JA, McNamara S, Purser M, et al. Multiple myeloma refractory to lenalidomide: A systematic literature review of trials and real-world evidence. Br J Haematol. 2024;205(3):780–797 8. National Institute for Health and Care Excellence (NICE). Belantamab mafodotin with bortezomib and dexamethasone for previously treated multiple myeloma (TA1149). April 2026 9. National Institute for Health and Care Excellence (NICE). Belantamab mafodotin with pomalidomide and dexamethasone for previously treated multiple myeloma (TA1133). February 2026 10. Hungria V, Robak P, Hus M, et al. Belantamab Mafodotin, Bortezomib, and Dexamethasone for Multiple Myeloma. N Engl J Med. 2024 Aug	

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		1;391(5):393-407. doi: 10.1056/NEJMoa2405090. Epub 2024 Jun 1. PMID: 38828933. 11. Dimopoulos MA, Beksac M, Pour L, et al. Belantamab Mafodotin, Pomalidomide, and Dexamethasone in Multiple Myeloma. N Engl J Med. 2024 Aug 1;391(5):408-421. doi: 10.1056/NEJMoa2403407. Epub 2024 Jun 2. PMID: 38828951. 12. EMC. Blenrep 100 mg powder for concentrate for solution for infusion. Accessed on May 2026. Available at: https://www.medicines.org.uk/emc/product/100782/ 13. EMC. Dexamethasone 2mg tablets. Accessed on May 2026. Available at: https://www.medicines.org.uk/emc/product/5411/	
	GlaxoSmithKline	Please see 'other considerations' section	Thank you for your comment. This topic has been entered into the work schedule.
	Myeloma UK	There is an urgent need from innovative treatments like cilta-cel. 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. CAR-T cell treatments have the potential to be transformative at several stages of the myeloma pathway, and patients tell us about the tangible mental and physical benefits of being able to access CAR-T as early as possible in the pathway. CAR-T cell treatments for myeloma have been available in other countries for 5 years and are available privately in the UK	Thank you for your comments. This topic has been entered into the work schedule.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Johnson & Johnson	The main aims of MM therapy are to prolong survival and maintain a good quality of life by controlling the condition and relieving symptoms. If the condition progresses after initial treatment, the choice of subsequent therapy is influenced by previous treatment and response to it, duration of remission, comorbidities and patient preference. Management of MM is still challenging, despite the recent emergence of proteasome inhibitors (PIs), immunomodulatory agents (IMiDs) and monoclonal antibodies. Treatment can induce remission for months or years, but patients may eventually relapse and/or become refractory to treatment, rendering the disease increasingly difficult to treat.[1,2] A growing number of patients become refractory to commonly used IMiDs such as lenalidomide, which not only results in a progressive narrowing of treatment options, but also presents a challenge due to impaired prognosis and poorer outcomes overall.[3-6] This subset of patients demonstrates shorter OS, PFS and time to next treatment compared to patients without lenalidomide refractoriness.[3,5-9] The current draft scope provides a general overview of RRMM management, but does not adequately recognise patients who are relapsed, lenalidomide-refractory. With lenalidomide now widely used in first-line indications including maintenance therapy, there is a growing population of patients presenting with lenalidomide refractoriness and thus further lenalidomide-based regimens in the later lines are no longer considered appropriate. This is reflected in the NICE draft scope for the population in this decision problem, where lenalidomide-containing regimens are excluded as relevant comparators. Therefore, J&J requests that the lenalidomide-refractory population be clearly distinguished from the general RRMM population, to	Thank you for your comments. The scope is intended to contain a brief overview of the available treatments recommended for multiple myeloma. No change to scope required.

Section	Consultee/ Commentator	Comments [sic]	Action
		ensure better alignment to the population in this appraisal, appropriate comparator selection and accurate reflection of the high unmet need and poor outcomes associated with this population. References: 1. Cook G, Cella D, Chen C, et al. Survival in Patients with Relapsed/Refractory Multiple Myeloma: Outcomes after 4 Years of the Ongoing Multinational Observational Preamble Study. *Blood*. 2018/11/29/ 2018;132:3285. doi:https://doi.org/10.1182/blood-2018-99-112081. 2. Myeloma UK. Treatment for relapsed myeloma. Accessed July 3, 2020, https://www.myeloma.org.uk/understanding-myeloma/treating-myeloma/treatment-for-relapsed-myeloma/. 3. Moreau P, Zamagni E, Mateos MV. Treatment of patients with multiple myeloma progressing on frontline-therapy with lenalidomide. *Blood Cancer J*. Mar 20 2019;9(4):38. doi:10.1038/s41408-019-0200-1. 4. Mateos MV, Gavriatopoulou M, Facon T, et al. Effect of prior treatments on selinexor, bortezomib, and dexamethasone in previously treated multiple myeloma. *J Hematol Oncol*. Apr 13 2021;14(1):59. doi:10.1186/s13045-021-01071-9. 5. Avet-Loiseau H, et al. . Poster EP1008 Treatment patterns of lenalidomide delivery and outcomes in multiple myeloma patients in real-world settings: A multi-center retrospective study. presented at: 25th Annual EHA Congress; June 11-21, 2020 2020; Virtual. 6. Hajek et al. 3204 Patient Characteristics and Survival Outcomes of Lenalidomide Exposed non- Refractory vs. Lenalidomide Refractory Multiple Myeloma Patients in the HONEUR Federated Data Network. . presented at: 64th American Society of Hematology Annual Meeting	

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		and Exposition 2022 (ASH 2022); 10-13 December 2022 2022; New Orleans, Louisiana. 7. Goel et al. 4492 Outcomes of Multiple Myeloma Patients Refractory to Standard Dose Vs Low Dose Lenalidomide. presented at: 64th American Society of Hematology Annual Meeting and Exposition 2022 (ASH 2022); 10-13 December 2022 2022; New Orleans, Louisiana. 8. Couto ME, Borges M, Bento MJ, et al. Treatment Patterns and Outcomes in Lenalidomide-Exposed Multiple Myeloma Patients in Real-World Settings: A Multi-Center Retrospective Study. *Blood*. 2021/11/23/ 2021;138:5012. doi:https://doi.org/10.1182/blood-2021-148724. 9. Lecat CSY, Taube JB, Wilson W, et al. Defining Unmet Need Following Lenalidomide Refractoriness: Real-World Evidence of Outcomes in Patients With Multiple Myeloma. *Front Oncol*. 2021;11:703233. doi:10.3389/fonc.2021.703233.	
	GlaxoSmithKline	'For people whose condition is relapsed or refractory after at least 1 prior therapy, NICE recommends:' the following treatment should be included: NICE technology appraisal 695 recommends carfilzomib plus lenalidomide and dexamethasone, after 1 line of treatment containing bortezomib.	Thank you for your comment. This technology appraisal was correctly listed in the second bullet of the list of available treatments. No change to scope required.
	Myeloma UK	We consider this information to be sufficient and accurate.	Thank you for your comment.
Population	Johnson & Johnson	J&J requests the population to be defined as follows, to align with licensed wording and inclusion criteria in the phase 3 CARTITUDE-4 trial: adult	Thank you for your comment. The

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		patients with relapsed and refractory multiple myeloma, who have received 1-3 prior therapies, including an IMiD and a PI, have demonstrated disease progression on the last therapy, and are refractory to lenalidomide.[1,2] References: 1. EMC. CARVYKTI 3.2 × $10^{6\,-1}$ × 10^{8} cells dispersion for infusion. Accessed on May 2026. Available at: https://www.medicines.org.uk/emc/product/100341 2. San-Miguel J, Dhakal B, Yong K, et al. Cilta-cel or Standard Care in Lenalidomide-Refractory Multiple Myeloma. N Engl J Med. 2023 Jul 27;389(4):335-347. doi: 10.1056/NEJMoa2303379. Epub 2023 Jun 5. PMID: 37272512.	population in the scope has been updated to better align with the license wording.
	GlaxoSmithKline	As outlined below – consideration should be given to the under representation of anti-CD38 exposed patients in the pivotal CARTITUDE-4 study. Given daratumumab's widespread use in frontline regimens in England, a substantially higher proportion of NHS patients presenting at first or second relapse will be daratumumab-refractory.	Thank you for your comment. No change to scope required.
	Myeloma UK	Yes, we believe the population is appropriately defined and aligned with the population recruited to CARTITUDE-4 clinical trial (received 1-3 prior lines of treatment). It is common in myeloma appraisals that final company submissions are narrower than full marketing authorisation. 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.	Thank you for your comment.

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Subgroups	Johnson & Johnson	No subgroups have been identified for which cilta-cel is expected to be more clinically-or cost effective. Given the significant unmet need and poorer survival outcomes in lenalidomide-refractory RRMM as outlined above, J&J advocates for cilta-cel to be made available to all eligible patients, without the need for separate subgroup considerations. **BCMA-exposed subgroup** Consistent with this position, J&J does not support the exploration of subgroup analyses based on prior exposure to BCMA-targeted therapies. The CARTITUDE-4 trial explicitly excludes patients with prior BCMA-targeted therapy, therefore, robust evidence to support such subgroup analyses is not feasible. Evidence suggests that selective antigen pressure with earlier BCMA-targeted antibody drug conjugates (ADCs) (e.g., belantamab) has been associated with significant biological changes, including loss or alteration of BCMA expression, in approximately 40% of patients.[1,2] These changes may impact the durability of response to subsequent CAR-T therapies targeting the same antigen, leading to poorer outcomes. The IMWG sequencing guidelines recommend prioritising BCMA-targeted CAR-T therapies ahead of alternative BCMA-directed modalities (e.g. ADCs), driven by the higher clinical activity of CAR-T and evidence suggesting reduced efficacy following prior exposure to BCMA-targeted ADCs. Furthermore, these guidelines recommend the use of bispecific antibodies after CAR-T therapy, reflecting stronger evidence supporting their activity in the post-CAR-T setting.[3] This is further aligned with the joint EHA–EMN guidance, which similarly supports the use of CAR-T therapy prior to ADCs and bispecific antibodies.[4]	Thank you for your comments.

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		Therefore, in the absence of trial data and based on expert recommendation on treatment sequencing, subgroup analyses in BCMA-exposed patients should be avoided in this appraisal as it is unlikely to yield reliable and interpretable outcomes. References: 1. Lee H, Ahn S, Maity R, Leblay N, Ziccheddu B, Truger M, et al. Mechanisms of antigen escape from BCMA- or GPRC5D-targeted immunotherapies in multiple myeloma. Nat Med. 2023;29:2295–306. 2. Truger MS, Duell J, Zhou X, Heimeshoff L, Ruckdeschel A, John M, et al. Single and double-hit events in genes encoding immune targets before and after T cell engaging antibody therapy in MM. Blood Adv. 2021;5:3794–8. 3. Costa, L.J., Banerjee, R., Mian, H. et al. International myeloma working group immunotherapy committee recommendation on sequencing immunotherapy for treatment of multiple myeloma. Leukemia 39, 543–554 (2025). https://doi.org/10.1038/s41375-024-02482-6 4. Van de Donk NWCJ, Moreau P, San-Miguel JF, Mateos MV, Dimopoulos MA, Zweegman S, et al. EMN Guidelines Committee. Sequencing BCMA- and GPRC5D-targeting immunotherapies in multiple myeloma: Practical guidance from the European Myeloma Network. Hemasphere. 2025 Nov 25;9(11):e70260. doi: 10.1002/hem3.70260. PMID: 41306326; PMCID: PMC12645799.	
	GlaxoSmithKline	No subgroups suggested.	Thank you for your comment.

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Comparators	Johnson & Johnson	Comparator selection should reflect the complex, contemporary NHS clinical practice for patients relapsing early following present frontline therapy for MM patients. The choice of therapy in RRMM is driven by multiple factors including prior treatment exposure, refractory status, toxicity profiles and patient tolerability. **Prior line of therapy** Patients enrolled in the CARTITUDE-4 trial, which represents the pivotal source of clinical evidence for cilta-cel in this decision problem, were required to have RRMM, be lenalidomide-refractory and have received 1-3 prior lines of therapy (including a PI and IMiD).[1] This is reflected in the UK marketing authorisation specifying cilta-cel for adult patients with RRMM who have received at least one prior therapy, including both an IMiD and a PI.[2] In line with both the CARTITUDE-4 trial inclusion criteria and marketing authorisation, J&J proposes revising the scope to compare cilta-cel with relevant therapies in the second to fourth line setting only, rather than including lines of therapy beyond fourth line. **Refractoriness to lenalidomide** All patients enrolled into the CARTITUDE-4 trial were lenalidomide-refractory, therefore, regimens containing lenalidomide in the second, third and fourth-line settings are not clinically appropriate comparators for cilta-cel. This is already appropriately reflected in the list of comparators presented in the draft scope. **Prior exposure to PI and IMiD**	Thank you for your comments. The comparators section of the scope is intended to be inclusive of the available treatments. Treatments subject to NICE evaluation can be considered a relevant comparator if final guidance will be published before the first committee meeting for the current topic. It is recognised that not all may be considered as relevant comparators by the company and this may be reflected in its choice of comparators in its evidence submission, with appropriate justification. Linvoseltamab monotherapy has been removed as a comparator because guidance will not be published at the time of

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		Finally, although several therapies are available for use in the second line setting and onwards, their use in practice for PI/IMiD-exposed RRMM is relatively limited or not reflective of established clinical practice. These considerations should be reflected in comparator selection. Therefore, J&J does not consider the following treatments included in the NICE draft scope as relevant comparators: • **Bortezomib monotherapy** is not a relevant comparator as it is not frequently used in the second line setting as indicated in TA974.[3,4] • **Isatuximab-pomalidomide-dexamethasone** is not a relevant comparator as it is not routinely commissioned in the UK at the time of scoping. • **Linvoseltamab monotherapy** is not a relevant comparator in the fourth line setting, as it is pending NICE guidance. Additionally, it is being evaluated in patients with triple-class exposed RRMM after 3 prior lines of therapy, thus representing a different treatment population to this cilta-cel decision problem. • **Anitocagtagene autoleucel [ID6549]** and **elranatamab [ID6653]** are currently being evaluated by NICE for patients who have had 3 or more prior therapies (triple class exposed). Although these treatments are intended for a distinct population with exposure or refractoriness to at least 3 prior lines of therapy, including a PI, an IMiD and an anti-CD38 therapy, J&J considers that they should be included in the scope for completeness, in line with the NICE manual, but excluded as relevant comparators. • **Teclistamab** and **talquetamab** should also be excluded as relevant comparators. NICE guidance positions these bispecific immunotherapies for people with triple-class exposed RRMM after 3	the first committee meeting for this appraisal. Bortezomib monotherapy has also been removed from the scope. No other change to comparators required.

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		prior lines of therapy. By contrast, patients eligible for cilta-cel would not be required to have prior exposure to anti-CD38 therapy and would therefore represent a different treatment population. • **Conventional chemotherapy regimens** and **best supportive care** are not suitable comparators to the cilta-cel population, as these are reserved for later lines in the treatment pathway as palliative options, after all other active agents have been exhausted. **Suggested new wording:** "For people who have had 1 previous therapy: • carfilzomib plus dexamethasone • daratumumab plus bortezomib and dexamethasone • selinexor plus bortezomib and dexamethasone • belantamab mafodotin with pomalidomide and dexamethasone • belantamab mafodotin with bortezomib and dexamethasone For people who have had 2 previous therapies: • panobinostat plus bortezomib and dexamethasone • selinexor plus bortezomib and dexamethasone For people who have had 3 previous therapies: • isatuximab plus pomalidomide and dexamethasone (subject to NICE evaluation) • panobinostat plus bortezomib and dexamethasone	

Section	Consultee/ Commentator	Comments [sic]	Action
		• pomalidomide plus dexamethasone • daratumumab monotherapy References: 1. San-Miguel J, Dhakal B, Yong K, et al. Cilta-cel or Standard Care in Lenalidomide-Refractory Multiple Myeloma. N Engl J Med. 2023 Jul 27;389(4):335-347. doi: 10.1056/NEJMoa2303379. Epub 2023 Jun 5. PMID: 37272512. 2. EMC. CARVYKTI 3.2 × $10^{6\,-1}$ × 10^{8} cells dispersion for infusion. Accessed on May 2026. Available at: https://www.medicines.org.uk/emc/product/100341 3. National Institute for Health and Care Excellence (NICE). Selinexor with bortezomib and low-dose dexamethasone for treating relapsed refractory multiple myeloma (TA974). May 2024. 4. National Institute for Health and Care Excellence (NICE). Bortezomib monotherapy for relapsed multiple myeloma (TA129). October 2007.	
	GlaxoSmithKline	The following treatments should be included as comparators: 'For people who have had 1 previous therapy:' • Mezigdomide with dexamethasone and carfilzomib (subject to NICE evaluation) • Anitocabtagene autoleucel (subject to NICE evaluation) • Teclistamab monotherapy (subject to NICE evaluation) 'For people who have had 2 previous therapies:'	Thank you for your comments. Technologies that are currently being appraised by NICE can be included as comparators (subject to NICE evaluation) only if a recommendation may have been made and implemented by the

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		• Mezigdomide with dexamethasone and carfilzomib (subject to NICE evaluation) • Anitocabtagene autoleucel (subject to NICE evaluation) • Teclistamab monotherapy (subject to NICE evaluation) 'For people who have had 3 or more previous therapies:' • Mezigdomide with dexamethasone and carfilzomib (subject to NICE evaluation) • Anitocabtagene autoleucel (subject to NICE evaluation)	time the technology that is being scoped is anticipated to have had its first committee meeting. No changes to scope required.
	Myeloma UK	We agree that the treatments listed could be available to relapsed and refractory meyloma patients, depending on the previous line(s) of treatment they have received. However, the list does not necessarily reflect current clinical practice. Under current clinical practice, the treatments below are typically used at each line: **Second line (after 1 previous therapy):** We would suggest that comparators based on current clinical practice are: - Daratumumab plus bortzeomib and dexamethasone - Belantamab mafodotin with pomalidomide and dexamethasone - Belantamab mafodotin with bortezomib and dexamethasone - Carfilzomib plus dexamethasone The combination of selinexor plus bortezomib and dexamethasone; and bortezomib monotherapy is not widely used in clinical practice at second line.	Thank you for your comments. The comparators section of the scope is intended to be inclusive of the available treatments recommended by NICE. It is recognised that not all treatments included will represent clinical practice and this may be reflected in the company's choice of comparators in its evidence submission, with appropriate justification. Bortezomib

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		Third line (2 previous therapies): We would suggest comparators are: - Selinexor plus bortezomib and dexamethasone - Cyclophosphamide and dexamethasone The combination of panobinostat plus bortezomib and dexamethasone for people who have had 2 and 3 previous therapies is not widely used in clinical practice. **Fourth line (3 previous therapies):** Based on current clinical practice, patients at fourth line are mainly receiving: - Talquetamab - Teclistamab - Elranatamab (via CDF) - Daratumumab - Isatuximab with pomalidomide and dexamethasone (via CDF) Linvoseltamab is currently going through the NICE appraisal process. It is not currently approved, so should not be considered a comparator. While pomalidomide plus dexamethasone (Pom-Dex) could be considered comparator at fourth line, Pom-Dex is considered salvage/end of life treatments. If a CAR-T or bispecific is suitable, it would be considered unethical to give Pom-Dex, considering their far shorter PFS and ORR.	monotherapy has been removed from the scope. No other changes to scope required.

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Outcomes	Johnson & Johnson	The outcomes listed are appropriate. However, J&J propose that minimal residual disease (MRD) negativity (including overall and sustained MRD negativity) be explicitly included as an additional response-based outcome measure, consistent with the CARTITUDE-4 endpoints that capture the most clinically meaningful benefit. MRD negativity is widely recognised as a marker of treatment response beyond complete response and is associated with improved long-term outcomes, including PFS and OS. Therefore, MRD negativity is increasingly considered a key indicator of treatment efficacy and is central to the concept of curative potential in MM.[1] The inclusion of MRD negativity as an outcome measure would therefore provide a more comprehensive assessment of treatment benefit of cilta-cel. This approach is aligned with NICE precedent, where MRD was included as an outcome measure in the appraisal of obecabtagene autoleucel (TA1116),[2] and daratumumab in combinations for untreated MM (TA763,[3] ID6249,[4] ID3843[5]), supporting its relevance as an endpoint in haematological malignancies. <u>References:</u> 1. María-Victoria Mateos et al. Moving Toward a Cure for Myeloma. Am Soc Clin Oncol Educ Book 42, 643-654(2022). 2. National Institute for Health and Care Excellence (NICE). Obecabtagene autoleucel for treating relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (TA1116). December 2025 3. National Institute for Health and Care Excellence (NICE). Daratumumab in combination for untreated multiple myeloma when a stem cell transplant is suitable (TA763). February 2022.	Thank you for your comments. MRD negativity would be captured under the outcome of response rate. No change to scope required.

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		4. National Institute for Health and Care Excellence (NICE). Daratumumab with bortezomib, lenalidomide and dexamethasone for untreated multiple myeloma when an autologous stem cell transplant is suitable (ID6249). Expected publication, August 2026. 5. National Institute for Health and Care Excellence (NICE). Daratumumab with bortezomib, lenalidomide and dexamethasone for untreated multiple myeloma when a stem cell transplant is unsuitable (ID3843). Expected publication, June 2026.	
	GlaxoSmithKline	Outcomes of the CARTITUDE studies should be carefully considered with regard given to the real world applicability. With regard to CARTITUDE 4 specifically: 1. Comparator Arms Not NHS-Commissioned Both SoC comparators in CARTITUDE-4 — DPd (87% of the control arm) and PVd (13%) — are not routinely funded by NHS England. NICE TA726 for DPd was terminated in 2021 following Janssen's withdrawal. The trial's comparator therefore does not reflect current NHS clinical practice, undermining the direct generalisability of the comparative efficacy and cost-effectiveness data. 2. Daratumumab-Refractory Rate Unrepresentative of the Contemporary UK Population Only 24% of the cilta-cel arm in CARTITUDE-4 were anti-CD38 refractory. Given daratumumab's widespread use in frontline regimens in England, a substantially higher proportion of NHS patients presenting at first or second relapse will be daratumumab-refractory.	Thank you for your comments. No change to scope required.

		3. Real-World Safety Rates Exceed Trial Data US real-world data (n=236) report higher rates of key toxicities than observed in CARTITUDE-4: CRS in 75%, ICANS in 14%, delayed neurotoxicity (DNT) in 10%, and Parkinsonism in 2%. DNT and movement disorders are clinically important cilta-cel-specific adverse events that require specialist neurological monitoring beyond the standard 100-day pathway — an infrastructure gap not reflected in current NHS CAR-T commissioning arrangements. 4. Bridging Therapy Unavailable in the NHS 87.8% of cilta-cel-arm patients in CARTITUDE-4 received DPd as bridging, and 12.2% PVd — neither commissioned on the NHS. Bridging therapy response is a significant determinant of post-CAR-T outcomes: patients achieving ≥VGPR on bridging had a 30-month OS of 91.4% versus 40% for those with progressive disease. A post-hoc analysis of outcomes in CARTITUDE-4 stratified by response to bridging therapy found poorer responses to bridging therapy were linked to fatal infections, prolonged thrombocytopenia and neutropenia, and higher rates of non-relapse mortality following cilta-cel infusion. Variation in bridging due to availability constraints has already been associated with heterogeneous outcomes across CAR-T products currently commissioned in England. 5. Manufacturing Failure Rate: Trial vs Real World CARTITUDE-4 reported zero manufacturing failures. Commercial real-world data show an overall out-of-specification or failure rate of approximately **18.9%**, declining from 34.8% in 2022 to 8.3% in early 2025 as processes matured. True manufacturing failures occur in approximately 2.9% of cases, with remanufacturing succeeding in ~50%. Any NHS economic model using a zero failure assumption will materially overestimate cost-effectiveness; ITT-based modelling incorporating a realistic failure probability is essential, particularly given the lack of established myeloma CAR-T pathway in the UK. Borogovac A, et al. Safety and efficacy of out-of-specification cilta-cel in RRMM. *Blood*. 2025;146(Suppl 1):405.	

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		Sidana S, Patel KK, Peres LC, et al. Safety and efficacy of standard of care ciltacabtagene autoleucel for relapsed/refractory multiple myeloma. Blood. 2024. DOI: 1182/blood.2024025945 Dulobdas V, et al. Risk factors for CAR T-cell manufacturing failure and patient outcomes in large B-cell lymphoma. *Blood Cancer Journal*. 2025;15(1):30. Zamagni E, et al. Effectiveness of bridging therapy corresponds to improved outcomes after ciltacabtagene autoleucel: phase 3 CARTITUDE-4 study. *Haematologica*. 2026;111(Suppl 2):P36. doi:10.3324/haematol.2026.s2.14045. Kirkwood AA, et al. Effective bridging therapy can improve CD19 CAR-T outcomes while maintaining safety in patients with large B-cell lymphoma. *Blood Adv.* 2023;7(12):2872–2883. doi:10.1182/bloodadvances.2022009019.	
	Myeloma UK	Yes, however it is worth noting that many of the key benefits from CAR-T are unlikely to be appropriately captured within the EQ-5D. This includes: financial, social and psychological benefits of a 'one-off' treatment over frequent hospital visits; benefits to patients families/carers; and of the treatment not including long-term steroids like dexamethasone which often have a significant and prolonged impact upon quality of life.	Thank you for your comments.
Equality	Johnson & Johnson	No equality issues have been identified.	Thank you for your comment.
	GlaxoSmithKline	No equality issues identified.	Thank you for your comment.
Other considerations	GlaxoSmithKline	The scope and subsequent appraisal should address the challenges and system implications of manufacturing and clinical infrastructure requirements. Including manufacturing turnaround time/ vein-to-vein time, manufacturing	Thank you for your comments.

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		failure rates, bridging therapy options and their costs, and management of adverse events including ICU bed blocking. Consideration should be given to the lack of established Myeloma pathway and the effect that a 'straight to early lines approach' will have on the number of patients becoming eligible following a positive recommendation. 1. Costing of CAR-T cell treatment tariff The economic model must accurately account for all costs associated with treatment (i.e. the updated CAR-T cell treatment tariff) from an NHS and personal social services (PSS) perspective. This is an issue that has been contended in previous appraisals of CAR-T cell treatment (i.e. ID6325 FDG, Section 3.13) 1. No Established Myeloma CAR-T Referral Pathway or National Panel No myeloma-specific National CAR-T Panel exists. The current NCCP was designed for lymphoma and ALL and has not been stress-tested for myeloma eligibility criteria, MDT structures, or the substantially larger patient volumes that 1–3 prior line eligibility would generate. The CGT Catapult / ATTC *Future-Proofing the UK CAR-T Patient Referral Pathway* report identified that the referral pathway has not materially changed since 2018, and explicitly calls for formalised referral processes, national infrastructure reform, and workforce training to support anticipated increases in CAR-T patient numbers and approved indications. The number of eligible myeloma patients would add significant strain to existing infrastructure. 2. Apheresis Capacity Already at Critical Limits NHS apheresis services were operating at 100% capacity as of 2022–2023, with demand having increased by 20% over the prior two years and a further 25% increase projected. The DHSC Apheresis Expert Working Group Report (March 2026) confirmed that physical space and nursing workforce are	

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		current constraints at 42% and nearly 100% of provider sites respectively, with all categories of constraint anticipated to worsen over the next 1–3 years. A myeloma CAR-T programme adding a significant number of leukapheresis procedures annually would directly compete with existing HSCT and CD19 CAR-T apheresis slots, consideration should be given to cost of expanding capacity. 3. NHS Service Specification Requirements Create Additional Downstream Pressure The NHS England CAR-T service specification mandates ITU access, critical care beds, pharmacy oversight for tocilizumab and immunoglobulin, and specialist nursing at all commissioned centres. These requirements — already stretching commissioned centres — would be intensified by a myeloma programme requiring cilta-cel-specific long-term neurological monitoring for delayed neurotoxicity beyond the standard 100-day pathway. Significant training gaps exist, including the absence of a nationally transferable apheresis nursing competency framework. Cost and burden of commissioning/delivery related to supportive medications such as tocilizumab, immunoglobulins and infection prophylaxis should also be considered. 4. Pathway Delays Drive Disease Progression and Ineligibility Real-world data demonstrate that decision-to-vein time is a major cause of harm in CAR-T pathways: systematic delays lead to disease progression, rendering patients ineligible before infusion, and are associated with inferior post-infusion outcomes. In the UK brexucabtagene autoleucel B-ALL programme, approximately 30% of NCCP-approved patients did not receive infusion, partly due to disease progression during the manufacturing and logistics period. With no established myeloma referral pathway, no commissioned bridging therapy, and apheresis operating at capacity, the risk of pathway-related attrition and progression in an NHS myeloma CAR-T	

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		programme is substantial and must be reflected in any ITT-based economic model. Final draft guidance. Brexucabtagene autoleucel for treating relapsed or refractory mantle cell lymphoma after 2 or more lines of systemic treatment (review of TA677) https://www.nice.org.uk/guidance/gid-ta11545/documents/674 CGT Catapult / ATTC Network. Future-Proofing the UK CAR-T Patient Referral Pathway. White Paper, November 2023. https://www.theattcnetwork.co.uk/wp-content/uploads/2023/11/FINAL-Catapult-Collaborative-working-Project-final-report-1.pdf CGT Catapult / Gilead / Janssen / Autolus. ATTC Bridging — CAR-T Patient Referrals Pathway Gap Analysis: Outcomes Summary. April 2024. https://www.jnj.com/innovativemedicine/uk/download/outcomes-summary-attc-bridging-car-t-patient-referrals-pathway-gap-analysis ATTC Network. Apheresis Horizon Scanning Infographic. 2023. https://www.theattcnetwork.co.uk/wp-content/uploads/2023/10/Apheresis-Horizon-Scanning-Infographic.pdf DHSC Apheresis Expert Working Group. Apheresis Capacity in England: Report of the Apheresis Expert Working Group. March 2026. https://www.gov.uk/government/publications/apheresis-capacity-in-england-report-of-the-apheresis-expert-working-group NHS England. CAR-T Therapy (All Indications, All Ages) Service Specification. April 2026. https://www.england.nhs.uk/wp-content/uploads/2026/04/cart-service-specification-commissioning-guidance-v1.0-1.pdf Castleton A, et al. A UK Intention-to-Treat Analysis of Brexucabtagene Autoleucel for Relapsed or Refractory Adult ALL. ASH 2024; Abstract 2823.	

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Questions for consultation	Johnson & Johnson	**Have all relevant comparators for ciltacabtagene autoleucel been included in the scope?** **See response in 'Comparators' section** **Which treatments are considered to be established clinical practice in the NHS for relapsed refractory multiple myeloma after:** • **one line of prior therapy?** • **two lines of prior therapy?** • **three or more lines of prior therapy?** **See response in "Comparators" section** **How should best supportive care be defined?** **See response in 'Comparators' section** **Are the outcomes listed appropriate?** **J&J propose adding (overall and sustained) MRD negativity as an additional response-based outcome measures based on the endpoints in the clinical trial that capture the most important health benefits.** **Are there any subgroups of people in whom ciltacabtagene autoleucel is expected to be more clinically effective and cost effective or other groups that should be examined separately?** **See response in "Subgroups" section.** **Where do you consider ciltacabtagene autoleucel will fit into the multiple myeloma treatment pathway in United Kingdom?** J&J consider that cilta-cel, aligned with its marketing authorisation, will fit as an option for patients who are lenalidomide-refractory and have received 1-3 prior therapies, including an IMiD and a PI and have demonstrated disease progression on the last therapy. **Would ciltacabtagene autoleucel be a candidate for managed access?** Routine access to CAR-T therapies ensure the UK is at the forefront of medical advances.	Thank you for your comments.

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		J&J plan to use long-term follow-up data from the phase 3 CARTITUDE-4 trial in the evidence submission to NICE. Clinical uncertainty discussed during the NICE process will not benefit from the maximum 5-year period of managed access. Therefore, J&J expect cilta-cel will be available via routine commission and therefore do not consider managed access to be appropriate. **NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:** • **could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which ciltacabtagene autoleucel /will be licensed;** • **could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;** • **could have any adverse impact on people with a particular disability or disabilities.** **Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.** **No issues have been identified in relation to the exclusion of any people protected by the equality legislation who fall within the patient**	

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		population or recommendations that have a different impact or adverse impact on people with particular disabilities. **Do you consider ciltacabtagene autoleucel to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?** Cilta-cel would be considered an innovative treatment with the potential to provide substantial health-related benefits in lenalidomide-refractory MM. Cilta-cel offers a **novel mechanism of action** as a BCMA-targeted CAR-T therapy and represents a **step-change** from existing treatments, which are typically delivered continuously and are associated with limited durability of response in this population. Clinical evidence demonstrates high response rates with **unprecedented deep and durable remissions**, raising the possibility of sustained long-term disease control and, for some patients, a **curative potential**[1], which is not achievable with current standard therapies. Cilta-cel addresses a high unmet need in patients who have received multiple prior therapies and have poor prognosis. Its single-administration is likely to reduce ongoing treatment burden and enable extended treatment-free intervals, with improved benefits for quality of life. While there are considerations related to toxicity management, manufacturing timelines, and service delivery, these do not detract from the innovative nature of cilta-cel or its potential to substantially improve patient outcomes and transform the current myeloma treatment pathway. References:	

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		1. Jagannath S, et al. Long-Term (≥5-Year) Remission and Survival After Treatment With Ciltacabtagene Autoleucel in CARTITUDE-1 Patients With Relapsed/Refractory Multiple Myeloma. J Clin Oncol. 2025 Sep;43(25):2766-2771 **Do you consider that the use of ciltacabtagene autoleucel can result in any potential significant and 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 Appraisal Committee to take account of these benefits**. The use of a CAR-T such as cilta-cel can result in potentially substantial health-related benefits. Cilta-cel is administered as a **one-time infusion** which would allow patients to experience prolonged treatment-free periods before further treatment is needed, which may be associated with improved quality of life.[1] This aligns with patient-reported preferences in MM, where longer remission and treatment-free periods are consistently identified as among the most important treatment outcomes.[2] Furthermore, cilta-cel is a **dexamethasone-free treatment**, thus significant impacts on the daily lives of patients from dexamethasone use, such as mood swings, aggression, mania, insomnia and fatigue, are mitigated.[3] This is particularly important as patients with MM frequently report treatment-related adverse events, such as fatigue, as major drivers of reduced quality of life and daily functioning.[2] These benefits of treatment may not be adequately captured in the QALY calculation, however, do remain as significant health-related benefits. References:	

Section	Consultee/ Commentator	Comments [sic]	Action
		1. Acaster S, et al. Impact of the treatment-free interval on health-related quality of life in patients with multiple myeloma: a UK cross-sectional survey. *Support Care Cancer*. **21**(2):599-607 (2013) 2. Myeloma UK. Measuring Patient Preferences: An exploratory study to determine how patient preferences data could be used in health technology assessment (HTA). Available at: https://www.myeloma.org.uk/wp-content/uploads/2024/09/NICE-Patient-Preferences-Report.pdf 3. EMC. Dexamethasone 2mg tablets. Accessed on May 2026. Available at: https://www.medicines.org.uk/emc/product/5411/smpc **To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly**. **Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts**. The UK has been at the forefront of approving, reimbursing and rolling out ATMPs to patients, including a number of CAR-Ts and gene therapies.[1-4] It is crucial that the UK builds on this experience, gained through both clinical trials and routine NHS delivery, to ensure these innovative treatments can benefit as many eligible patients as possible. There is extensive real-world NHS experience of providing these therapies to patients, and it is now vital that the NHS continues to build and enhance its service readiness to deliver them at greater efficiency and at scale. There are significant numbers of ATMPs in varying stages of clinical development in multiple disease areas.[5] Ensuring national service readiness	

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		must be supported by effective workforce planning alongside opportunities to realise economies of scale and achieve greater integration with manufacturer supply chains and NHS service delivery. Government policies already support the accelerated approval and adoption of life sciences innovation.[6-9] Building on this, it is essential that this is matched by continued and sufficient resource allocation to ensure equitable adoption of CAR-T therapies and ATMPs in patient-convenient settings across the UK. References: 1. National Institute for Health and Care Excellence (NICE). Lisocabtagene maraleucel for treating relapsed or refractory large B-cell lymphoma after first-line chemoimmunotherapy when a stem cell transplant is suitable (TA1048). March 2025. 2. National Institute for Health and Care Excellence (NICE). Axicabtagene ciloleucel for treating relapsed or refractory diffuse large B-cell lymphoma after first-line chemoimmunotherapy (TA895). June 2023. 3. National Institute for Health and Care Excellence (NICE). Brexucabtagene autoleucel for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people 26 years and over (TA893). June 2023. 4. National Institute for Health and Care Excellence (NICE). Axicabtagene ciloleucel for treating diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma after 2 or more systemic therapies (TA872). February 2023. 5. Morris W, Duffy D. The future of cell and gene therapies in the UK: Skills, training and development. LifeArc. 2023. Available at:	

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		https://publicpolicyprojects.com/wp-content/uploads/2023/06/Cell-Gene-Report.pdf 6. GOV.UK. Life Sciences Sector Plan (Policy paper). 16 July 2025. Available at: https://www.gov.uk/government/publications/life-sciences-sector-plan 7. GOV.UK. 10 Year Health Plan for England: fit for the future (Policy paper). 3 July 2025. Available at: https://www.gov.uk/government/publications/10-year-health-plan-for-england-fit-for-the-future 8. GOV.UK. National Cancer Plan for England (Policy paper). 4 February 2026. Available at: https://www.gov.uk/government/publications/national-cancer-plan-for-england 9. GOV.UK. Arrangement between the United States of America and the United Kingdom on pharmaceutical pricing (HTML) (Policy paper). April 2026. Available at: https://www.gov.uk/government/publications/uk-us-arrangement-on-pharmaceutical-trade-and-pricing/arrangement-between-the-united-states-of-america-and-the-united-kingdom-on-pharmaceutical-pricing-html	
	Myeloma UK	**Where do you consider ciltacabtagene autoleucel will fit into the multiple myeloma treatment pathway in United Kingdom?** It is likely that cilta-cel would become the preferred treatment at the earliest line possible for those eligible. Clinically, and in relation to health related quality of life, there are physical and psychological benefits to giving CAR-T at this earliest stage when treatment burden is lower. The presence of BCMA-targeting treatments at second line (belantamab) and fourth line (teclistamab and elranatamab) mean that there are treatments with	Thank you for your comments.

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		the same target to cilta-cel. The International Myeloma Working Group's sequencing highlights further evidence is needed, but that it may be beneficial to give CAR-T before other BCMA-targeting treatments as there is a risk of T-cell exhaustion from the prior CAR-T expansion of T-cells; or to ensure that there is sufficient breaks (>6 months) between targeted immunotherapy treatments. After cilta-cel, a treatment with a different mechanism of action like talquetamab may be more likely to be selected rather than BCMA-target treatments if it is available and suitable for that patient. However, flexibility in the myeloma pathway is fundamental. Patients move through lines of treatment, become refractory, may experience adverse affects or can be unable to access treatment for other reasons. There is variation in how treatments are used, who gets them, and when. The pathway is also rapidly changing. Having a range of options available to patients, with flexibility in when they are given, enables the best, tailored treatment to be given. Applying restrictions to the sequencing means that patients who fall outside the standard pathway may not be able to access effective treatment, and may lead to unnecessary challenges in the future as new treatments emerge and enter the pathway. **Would ciltacabtagene autoleucel be a candidate for managed access?** Yes **Do you consider that the use of ciltacabtagene autoleucel can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?**	

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		Yes. Unlike most myeloma treatments, ciltacabtagene autoleucel is given as a one-off treatment. For patients and carers, this reduces number of hospital visits for treatment treatment. This has significant psychosocial and financial benefits, which are unlikely to be captured by EQ-5D. Long remission and time off treatment are one of the biggest benefits which patients tell us about.	
Additional comments on the draft scope	GlaxoSmithKline	Under **'related NICE recommendations:'** a hyperlink and 'TA1149' should be added to: Belantamab mafodotin with bortezomib and dexamethasone for previously treated multiple myeloma (2026) NICE technology appraisal guidance XX. Under **'related appraisals in development (excludes suspended):'** the following appraisals should be added: **Project information | Anitocabtagene autoleucel for treating relapsed or refractory multiple myeloma ID6549 | Guidance | NICE** **Project information | Mezigdomide with dexamethasone and carfilzomib for treating relapsed or refractory multiple myeloma after at least 1 line of treatment ID6513 | Guidance | NICE** **Project information | Teclistamab for treating relapsed or refractory multiple myeloma after 1 or more treatments ID6628 | Guidance | NICE**	Thank you for your comments. These have been updated in the scope.

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	Myeloma UK	CAR-T cell treatments often require bridging treatment between T-cell collection and delivery of cells. These are often other NHS approved treatments for myeloma. This needs to be considered with sequencing to ensure that patients are not disadvantaged when receiving ciltacabtagene autoleucel.	Thank you for your comment.

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