National Institute for Health and Care Excellence

Health Technology Evaluation

Anitocabtagene autoleucel for treating relapsed or refractory multiple myeloma ID6549
Response to stakeholder organisation comments on the draft remit and draft scope

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Comment 1: the draft remit and proposed process

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	Gilead Sciences (Company)	The need for an appraisal is appropriate, and the Company agrees with the proposed single technology appraisal (STA) evaluation route	Comments noted. No action is needed.
	Myeloma UK	No comments	No action is needed.
	GlaxoSmithKline	The topic and proposed evaluation route are appropriate.	Comment noted. No action is needed.
	Johnson & Johnson Innovative Medicine	The proposed evaluation route (i.e., STA) is appropriate.	Comment noted. No action is needed.
	Pfizer	No comments	No action is needed.

Section	Stakeholder	Comments [sic]	Action
Wording	Gilead Sciences (Company)	The wording of the remit is appropriate.	Comment noted. No action is needed.
	Myeloma UK	Myeloma UK considers the remit to reflect the issues of clinical and cost effectiveness.	Comment noted. 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.	Comment noted. No action is needed.
	Johnson & Johnson Innovative Medicine	The wording of the remit is appropriate.	Comment noted. No action is needed.
	Pfizer	No comments	No action is needed.
Timing issues	Gilead Sciences (Company)	There is a high unmet need in patients with relapsed and/or refractory multiple myeloma (RRMM), driven by limited effective treatment options and extremely poor prognosis. Current treatment options for these patients are continuous therapies, which can impose an additional treatment burden on an already heavily pre-treated population, as well as on the NHS. In addition, many patients are refractory to the three major backbone drug classes in MM treatment (immunomodulatory drugs (IMiD), proteasome inhibitors (PI), and anti-CD38 monoclonal antibodies), which limits subsequent treatment options. Therefore, there is an urgent need for a novel, highly efficacious, one-time treatment delivering a durable response, such as anitocabtagene autoleucel (anito-cel). In this context, Gilead would like to secure reimbursement for anito-cel as early as possible to enable timely patient access.	Comments noted. NICE aims to provide draft guidance to the NHS within 6 months from the date when the marketing authorisation for a technology is granted. NICE has scheduled this topic into its work programme. See the NICE website: https://www.nice.org.uk/guidance/indevelopmen

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			t/gid-ta11722. No action is needed.
	Myeloma UK	There is an urgent need from innovative treatments like anito-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. CAR-T cell treatments for myeloma have been available in other countries for 5 years[1] and are available privately in the UK References 1. Mitra, A., Barua, A., Huang, L., Ganguly, S., Feng, Q., & He, B. (2023). From bench to bedside: the history and progress of CAR-T cell therapy. Frontiers in immunology, 14, 1188049. https://doi.org/10.3389/fimmu.2023.1188049	Comments noted. NICE aims to provide draft guidance to the NHS within 6 months from the date when the marketing authorisation for a technology is granted. NICE has scheduled this topic into its work programme. See the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ta11722. No action is needed.
	GlaxoSmithKline	Considering the currently reimbursed treatments (and potential therapies currently undergoing appraisal), there are a number of effective therapeutic options in each of the lines of treatment in scope (1-3). At the time of writing, the available data from registrational trials for anitocabtagene autoleucel in earlier lines (1-2 prior lines of therapy), combined with a number of effective options in second and third line, would suggest a low urgency in the NHS based on current evidence.	Comments noted. NICE aims to provide draft guidance to the NHS within 6 months from the date when the marketing authorisation for a technology is granted. NICE has

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		However, given the poor outcomes in patients who have received three prior line of therapy and the data from the IMMagine-1 phase 2 study demonstrating efficacy that surpasses the outcomes of currently available therapies in the setting, an argument could be made for moderate urgency in the later line setting.	scheduled this topic into its work programme. See the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ta11722. No action is needed.
	Johnson & Johnson Innovative Medicine	No comment	No action is needed.
	Pfizer	No comment	No action is needed.
Additional comments on the draft remit	Gilead Sciences (Company)	No further comments	No action is needed.
	GlaxoSmithKline	N/A	No action is needed.
	Pfizer	No comment	No action is needed.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Gilead Sciences (Company)	Gilead is planning to define the population in the appraisal in line with the Phase II open-label, single-arm, multicentre study (iMMagine-1):	Comments noted. The scope has been kept broad to ensure that NICE can appraise the

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		Adult patients with RRMM after three or more prior therapies including a PI, an IMiD, and an anti-CD38 monoclonal antibody. Therefore, only NICE guidance in the 4L+ setting is relevant to this appraisal.	technology within its marketing authorisation. No action is needed.
	Myeloma UK	We consider this information to be sufficient and accurate.	Comment noted. No action is needed.
	GlaxoSmithKline	**'For people who have had at least 1 prior treatment' the following treatment should be included:** Belantamab mafodotin with pomalidomide and dexamethasone for previously treated multiple myeloma [TA1133] • Technology appraisal guidance was published 18 February 2026	Comments noted. The scope has been updated.
	Johnson & Johnson Innovative Medicine	The background information is described appropriately.	Comment noted. No action is needed.
	Pfizer	No comment	No action is needed.
Population	Gilead Sciences (Company)	The population defined in the draft scope reflects a broader population than that investigated in the iMMAGINE-1 trial supporting this submission The appropriate population for this scope is adult patients with RRMM* after three or more prior therapies including a PI, an IMiD, and an anti-CD38 monoclonal antibody. This is in line with the iMMagine-1 trial *RRMM is defined as relapsed and/or refractory multiple myeloma, not relapsing or remitting multiple myeloma as stated in the draft scope	Comments noted. iMMAGINE-3 included people with relapsed or refractory multiple myeloma who had 1 to 3 lines of prior treatment. The scope has been kept broad to ensure that NICE can

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			appraise the technology within its marketing authorisation. No action is needed.
	Myeloma UK	We believe the population should be more defined. It is likely that the MHRA licence will be based on the phase 2, iMMagine-1 clinical trial. Data from this trial was recently presented at international conferences. This trial only recruited patients who have had three previous treatments and therefore the indication for this treatment is likely to be in this patient group. 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	Comments noted. iMMAGINE-3 included people with relapsed or refractory multiple myeloma who had 1 to 3 lines of prior treatment. The scope has been kept broad to ensure that NICE can appraise the technology within its marketing authorisation. No action is needed.
	GlaxoSmithKline	Multiple myeloma is not a 'relapsing and remitting' condition. This should be corrected to 'relapsed or refractory' multiple myeloma.	Comments noted. The scope has been updated.
	Johnson & Johnson Innovative Medicine	Relapsed or refractory multiple myeloma (RRMM) encompasses a broad and heterogeneous group of patients. It is important to more precisely define the technology's intended target population. Within the 'Technology' section of the draft scope, it is stated that the intervention is currently being evaluated in clinical trials involving patients with relapsed or refractory multiple myeloma (RRMM) who have received at least 1 to 3 prior lines of therapy.	Comments noted. iMMAGINE-3 included people with relapsed or refractory multiple myeloma who had 1 to 3 lines of prior treatment. The scope

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		However, the NIHRIO briefing document, presented under 'Topic prioritisation' for ID6549, indicates that RRMM after at least 3 prior lines of therapy is the target indication for anito-cel in this appraisal: - The primary clinical trial referenced in the briefing document is the iMMagine-1 Phase 2 study (NCT05396885), which enrolled patients with relapsed or refractory multiple myeloma (RRMM) who had received ≥ 3 prior lines of therapies, including a proteasome inhibitor (PI), immunomodulatory drug (IMiD), and an anti-CD38 antibody, and who were refractory to their last line of therapy. - The recommended treatment options for anito-cel are those technologies currently endorsed for individuals who have undergone at least three previous treatments. To resolve the inconsistency regarding the proposed indication and allow stakeholders to provide relevant evidence for decision-making, Johnson & Johnson recommends redefining the target population to clarify the intervention's positioning in the MM treatment pathway. Therefore, in line with the inclusion criteria of the iMMagine-1 trial, the population should be "*Relapsed or refractory multiple myeloma treated with at least 3 prior regimens of systemic therapy including proteasome inhibitor, immunomodulatory drugs (IMiD) and anti-CD38 antibody and are refractory to the last line of therapy*". References: • NIHRIO Health Technology Briefing. Anitocabtagene autoleucel for relapsed or refractory multiple myeloma. 2024. Available at: https://io.nihr.ac.uk/wp-content/uploads/2024/12/35154-	has been kept broad to ensure that NICE can appraise the technology within its marketing authorisation. No action is needed.

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		Anitocabtagene-Autoleucel-for-Multiple-Myeloma-V1.0-DEC2024-NON-CONF.pdf • ClinicalTrials.gov. A Phase II Study of CART-ddBCMA for the Treatment of Patients With Relapsed or Refractory Multiple Myeloma. Trial ID: NCT05396885. Available at: https://clinicaltrials.gov/study/NCT05396885	
	Pfizer	No comment	No action is needed.
Subgroups	Gilead Sciences (Company)	Given the substantial unmet need and poor outcomes in later-line MM treatment, Gilead considers that anito-cel should be made available to all patients who meet the marketing authorisation criteria.	
	Myeloma UK	No comments	No action is needed.
	GlaxoSmithKline	No subgroups suggested.	Comment noted. No action is needed.
	Johnson & Johnson Innovative Medicine	As outlined in the background section, the selection of treatment is determined by previous exposure to alternative mechanisms of action or drug classes. BCMA- and GPRC5D-targeting T-cell engagers are accessible through the NHS for RRMM patients. These treatments use a redirecting mechanism or a target (i.e. BCMA) similar to anito-cel. Alongside the proposed subgroup analysis based on previous lines of therapy, it may be valuable to consider a subgroup analysis by prior T-cell redirection therapy, should relevant data be available.	Comments noted. The scope has been updated.
	Pfizer	No comment	No action is needed.

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Comparators	Gilead Sciences (Company)	Gilead considers the following two comparators to be relevant in this submission: · Teclistamab monotherapy · Talquetamab monotherapy In the talquetamab technology appraisal (TA1114), NICE concluded that teclistamab was the only suitable comparator in the 4L+ setting, and did not consider PI-, IMiD-, or anti-CD38-based regimens to be appropriate comparators. Therefore, for the anito-cel target population - who have prior exposure to these therapy classes - regimens based on PIs, IMiDs, or anti-CD38 agents should likewise not be considered appropriate comparators. <u>Proteasome inhibitors</u> PI-based regimens are not typically used beyond second or third line. In addition, patients eligible for anito-cel will have been previously exposed to a PI, and re-challenge would not be a preferred option. We therefore propose that bortezomib-, carfilzomib- and ixazomib-based regimens are excluded from the scope: · **bortezomib** monotherapy (TA129) · carfilzomib plus dexamethasone (TA657) · **carfilzomib** plus lenalidomide and dexamethasone (TA695) · **ixazomib** plus lenalidomide and dexamethasone (TA870) <u>Anti-CD38 monoclonal antibodies</u> While daratumumab monotherapy (TA783) is recommended for patients with RRMM after 3 prior therapies, in current clinical practice, patients are expected to have received it in earlier lines (for example, daratumumab in	Comments noted. At this early stage, all treatments have been retained to keep the scope broad to account for the marketing authorisation, and relevant in the event of potential changes including delays to the company submission. Comparators from evaluations in development have been included, where applicable, and noted as “subject to NICE evaluation”. The company will have the opportunity during the full evaluation to outline which comparators it considers to be most relevant to its decision problem.

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		combination with bortezomib and dexamethasone; TA897). Since patients would not be routinely re-challenged with anti-CD38, daratumumab-based regimens should not be considered relevant comparators for the population in scope: · **daratumumab** monotherapy (TA783) · **daratumumab** plus bortezomib and dexamethasone (TA897) <u>Immunomodulatory drugs</u> While certain IMiDs are recommended at 4L+ for patients who have received at least 3 prior therapies, in practice these regimens are most commonly used earlier in the treatment pathway. Anito-cel-eligible patients will likely have been previously exposed to these drug classes. As such, these regimens are not considered relevant comparators in this appraisal: · **lenalidomide** plus dexamethasone (TA171) · **pomalidomide** plus low-dose dexamethasone (TA870) · ixazomib plus **lenalidomide** and dexamethasone (TA870) The talquetamab technology appraisal (TA1114) concluded that teclistamab and talquetamab are clinically superior and cost-effective options compared with selinexor, panobinostat and pomalidomide. In addition, **selinexor plus bortezomib and dexamethasone is not used further than in the second line.** We therefore propose that these treatments are excluded: · **panobinostat** plus bortezomib and dexamethasone (TA380) · **selinexor** plus bortezomib and dexamethasone (TA974) · **selinexor** plus dexamethasone (TA970) · **pomalidomide** plus low-dose dexamethasone (TA427)	

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		Lastly, treatments recommended in the Cancer Drugs Fund (elranatamab monotherapy; TA1023 and isatuximab plus pomalidomide and dexamethasone; TA658) as well as treatments currently subject to NICE evaluation, should not be included as comparators in accordance with section 2.2.15 of NICE technology appraisal and highly specialised technologies guidance: the manual. References: 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. Leukemia. 2012 Jan;26(1):149–5	
	Myeloma UK	We agree that the treatments listed available to relapsed and refractory meyloma patients, depending on the previous line(s) of treatment they have received. As the treatment is likely to be available after at least three prior treatments we would consider the main comparators to be bispecifics (teclistamab and talquetamab). In clinical practice myeloma patients who have had 3 prior treatments would typically recieve: • Teclistamab • Elranatamab (via CDF) • Talquetamab • Clinical trial • Compassionate use / Early access scheme	Comments noted. At this early stage, all treatments have been retained to keep the scope broad to account for the technology's marketing authorisation, and relevant in the event of potential changes in scheduling. Comparators from evaluations in development have been included, where applicable, and noted as "subject to NICE evaluation". The

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		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. The lenalidomide containing combination are not widely used at fourth line and beyond as majority of patients will be refractory to lenalidomide because they have received lenalidomide at previous lines of treatment. While selinexor plus dexamethasone (Sd) or pomalidomide plus dexamethasone (Pom-Dex) could be considered comparators at fourth/fifth line, both Sd and Pom-Dex are considered salvage/end of life treatments. If a CAR-T or bispecific is suitable, it would be considered unethical to give Sd or Pom-Dex, considering their far shorter PFS and ORR. We therefore would not consider Pom-Dex or Sd a comparator to CAR-T. While Isa-Pd could be a comparator, only a very small number of patients would be eligible to receive this because it requires patients to be unexposed to anti-CD38 therapies. Most patients will have received at least one (often, daratumumab) NICE appraisals for [mezigdomide with dexamethasone and carfilzomib] and [teclistamab plus daratumumab] have not started scoping and therefore should not be included as comparators in this appraisal.	company will have the opportunity during the full evaluation to outline which comparators it considers to be most relevant to its decision problem.
	GlaxoSmithKline	Belantamab mafodotin plus pomalidomide and dexamethasone is no longer '(subject to NICE evaluation)' as technology appraisal guidance was published 18 February 2026	Comments noted. The scope has been updated.

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		• Belantamab mafodotin with pomalidomide and dexamethasone for previously treated multiple myeloma [TA1133] Ciltacabtagene autoleucel has not been included and is a prospective comparator (subject to NICE evaluation) • Ciltacabtagene autoleucel for treating relapsed and lenalidomide-refractory multiple myeloma after 1 to 3 therapies [ID4012]	
	Johnson & Johnson Innovative Medicine	The list of comparators should be revised to reflect the redefined target population for this appraisal (see comments in the 'Population' section above). For people who have received at least 3 prior lines of treatment, linvoseltamab (ID6609) and elranatamab (ID6653) should be added as comparators in (subject to NICE evaluation).	Comments noted. At this early stage, all treatments have been retained to keep the scope broad to account for the technology's marketing authorisation, and relevant in the event of potential changes in scheduling. In line with the guidance provided in the company submission user guide: "1.3.3 Outline all potential comparators for the decision problem for this appraisal. A potential comparator is one which has final guidance before the first committee meeting for

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			the appraisal of the intervention in question", only elranatamab, isatuximab plus pomalidomide and dexamethasone and linvoseltamab have been included subject to NICE evaluation.
	Pfizer	**Comment 1** Please note elranatamab is currently in the CDF. It is mentioned in the draft scope page 2 but is **not** in the PICOS table. Please could this be added also. *"elranatamab after 3 or more lines of treatment including an immunomodulatory drug, a proteasome inhibitor and an anti-CD38 antibody (NICE technology appraisal guidance 1023).* **Comment 2** Please could you review recommendation wording for all treatments to align with NICE website recommendations. For example, • NICE technology appraisal guidance 1015 recommends teclistamab as a treatment option for adults who have had at least 3 previous treatments. Should read,	Comments noted. In line with section 2.2.15 of NICE technology appraisal and highly specialised technologies guidance: the manual which states that "Technologies that NICE has recommended with managed access are not considered established practice in the NHS and are not considered suitable comparators", elranatamab was initially not included in the list of comparators.

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		• Recommends teclistimab as an option for treating relapsed and refractory multiple myeloma in adults, only after 3 or more lines of treatment (including an immunomodulatory drug, a proteasome inhibitor and an anti-CD38 antibody) when the myeloma has progressed on the last treatment. • From our review the elranatamab and Isatuximab pomalidomide dexamethasone wording is also inconsistent with current NICE recommendation wording and should include its version of, "progressed on the last treatment".	However, elranatamab, isatuximab plus pomalidomide and dexamethasone and linvoseltamab have now been included as comparators, subject to NICE evaluation. This is because TA1023 is under review in ID6653, and falls in line with the guidance provided in the company submission user guide: "1.3.3 Outline all potential comparators for the decision problem for this appraisal. A potential comparator is one which has final guidance before the first committee meeting for the appraisal of the intervention in question." The background section of the scope provides a brief overview for the evaluation. Hyperlinks to the relevant

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			technology appraisal guidance have been included, where the full recommendation wording is available. Nevertheless, for consistency, the phrase “and the myeloma had progressed on the last treatment” has been added where relevant.
Outcomes	Gilead Sciences (Company)	The outcomes listed are appropriate.	Comment noted. No action is needed.
	Myeloma UK	Yes	Comment noted. No action is needed.
	GlaxoSmithKline	The iMMagine-3 trial dual primary endpoint of MRD rate and CR. • Is MRD intended to be used as a surrogate? • If so, what is the methodology for surrogacy thresholds?	Comments noted. ‘Minimal residual disease (MRD)’ and ‘complete response (CR)’ are covered by the outcome ‘response rates’ included in the scope. No action is needed.
	Johnson & Johnson	The outcomes listed are appropriate	Comment noted. No action is needed.

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	Innovative Medicine		
	Pfizer	No comment	No action is needed.
Equality	Gilead Sciences (Company)	RRMM predominantly affects patients in later life, with one-third of patients diagnosed with MM at age ≥75years.[1] Older patients have increased incidence of comorbidities, such as cardiovascular disease and renal insufficiency.[1] Gilead want to highlight potential equality considerations for older patients (and those with related disabilities/comorbidities) to ensure the remit and scope do not inadvertently disadvantage these groups in practice. It is important the scope supports equitable access to effective treatment options for this older population, helps address the significant unmet need in heavily pre-treated RRMM, and recognises the importance of reducing treatment burden (via a one-time infusion) where continuous, high-frequency therapies may disproportionately impact older and more comorbid patients. References: 1. Hari P, Romanus D, Luptakova K, et al. The impact of age and comorbidities on practice patterns and outcomes in patients with relapsed/refractory multiple myeloma in the era of novel therapies. J Geriatr Oncol. 2018; 9(2):138–44	Comments noted. In line with other technology appraisals in multiple myeloma, these equality issues will be considered by the committee during the evaluation. No action is needed.
	Myeloma UK	No comments	No action is needed.
	GlaxoSmithKline	No equality issues identified.	Comment noted. No action is needed.
	Johnson & Johnson	No equality issues have been identified.	Comment noted. No action is needed.

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	Innovative Medicine		
	Pfizer	No comment	No action is needed.
Other considerations	Gilead Sciences (Company)	Anito-cel offers the advantage of a one-time infusion, reducing healthcare resource use associated with ongoing therapies. It also materially reduces the treatment burden for patients who have already undergone prolonged, intensive therapy. CAR-T therapies usually require monitoring for severe toxicities: cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS). However, in the iMMagine-1 trial, anito-cel showed a more favorable safety profile than other approved CAR-T therapies: grade 3 ICANS occurred in one patient, and 1 incident of grade ≥3 CRS was observed. We anticipate that anito-cel could be delivered in an ambulatory care setting for a large proportion of patients. Where outpatient delivery is feasible, this is expected to provide meaningful benefits for patients and carers, including greater convenience and comfort, reduced time spent in hospital, and improved ability to maintain independence and quality of life. From an NHS perspective, outpatient delivery has the potential to reduce healthcare resource use by lowering inpatient bed days and associated staffing requirements, enabling more efficient use of specialist centre capacity.	Comments noted. The company will have an opportunity to outline the benefits of the technology in its submission. No action is needed.
	Myeloma UK	No additional suggestions	Comment noted. No action is needed.
	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	Comments noted. It is expected that relevant resource use,

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		failure rates, bridging therapy options and their costs, and management of adverse events including ICU bed blocking.	implementation considerations, and associated costs will be taken into account in the economic evaluation where appropriate. No action is needed.
	Johnson & Johnson Innovative Medicine	No comment	No action is needed.
	Pfizer	No comment	No action is needed.
Questions for consultation	Gilead Sciences (Company)	**Where do you consider anitocabtagene autoleucel will fit into the existing care pathway for relapsing or remitting multiple myeloma?** • Gilead considers anito-cel as a treatment option for adult patients with RRMM after three or more prior therapies including a PI, an IMiD, and an anti-CD38 monoclonal antibody **Please select from the following, will anitocabtagene autoleucel be**: • Prescribed in secondary care with routine follow-up in secondary care. **For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention**. • Prescribed in secondary care with routine follow-up in secondary care. **Would anitocabtagene autoleucel be a candidate for managed access?**	Comments noted. No action is needed.

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		• Gilead is awaiting longer follow-up data from the trial supporting this appraisal. As such, Gilead have not yet assessed whether anito-cel could be a candidate for managed access. **Do you consider that the use of anitocabtagene autoleucel can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?** • Anito-cel offers a one-time infusion that can deliver a durable response. Avoiding continuous treatment may improve quality of life for patients who have already endured prolonged courses of therapy. This benefit has been acknowledged by the EAG in its appraisals of obecabtagene autoleucel (obe-cel) for B-cell precursor acute lymphoblastic leukemia (TA1116, 2025) and lisocabtagene maraleucel (liso-cel) for diffuse large B-cell lymphoma (TA1048, 2025). However, formally incorporating this benefit into a cost-effectiveness analysis may be challenging. **Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits**. • Gilead is awaiting follow-up data from the trial that may have evidence to support the health-related benefits that are unlikely to be captured in the QALY. • As indicated, in the iMMagine-1 trial, anito-cel showed a more favorable safety profile than other approved CAR-T therapies: grade 3 ICANS occurred in one patient, and 1 incident of grade ≥3 CRS was observed. Historical CAR-T therapies have required monitoring for severe toxicities: cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS). The safety profile of anito-cel is such that there is likely to be a reduction in	

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		burden on the patient and carer, which is likely to have a positive benefit, that will be hard to quantify in the QALY. **Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.** • Not applicable	
	Myeloma UK	**Where do you consider anitocabtagene autoleucel will fit into the existing care pathway for relapsing or remitting multiple myeloma?** The trial recruited patients who have already received at least three previous treatments. It is therefore likely the indication for this treatment is to be for this patient group. Current clinician opinion suggests that CAR-T will be used in the treatment pathway ahead of bispecifics to ensure best patient outcomes. Patients are acutely aware as they move further and further through the pathway that achieving long periods of deep remission becomes increasingly difficult. CAR-T has a vital role to play here in providing patients with treatment options that have long, durable periods of remission and therefore will be used at the earliest opportunity. **Would anitocabtagene autoleucel be a candidate for managed access?**	Comments noted. No action is needed.

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		We believe that anitocabtagene autoleucel would be a candidate for managed access. Clinical trial data on progression free survival and overall survival is not publicly available beyond presentation at international conferences. **Do you consider that the use of anitocabtagene autoleucel can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?** 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. Results from CAR-T cell treatments in trial, private healthcare, and overseas suggest that they are transformative for patients with heavily pretreated myeloma with exceptional response rates and deep, durable remissions. Often this is achieved in patients who had exhausted other treatment options. CAR-T cell treatments are also unique in that they are given as a one-off treatment. A patient will have the treatment and then only receive monitoring. This is revolutionary compared to weekly or fortnightly administration of comparator bispecifics available at the same line of treatment. The one-off treatment offers distinct social, financial, practical and psychological QoL advantages to patients through fewer hospital visits and needs for ongoing medical intervention than all other myeloma treatments. The impact of this on patients, their families, and care, cannot be understated.	
	GlaxoSmithKline	N/A	No action is needed.

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	Johnson & Johnson Innovative Medicine	**Where do you consider anitocabtagene autoleucel will fit into the existing care pathway for relapsing or remitting multiple myeloma? Please select from the following, will anitocabtagene autoleucel be:** **A. Prescribed in primary care with routine follow-up in primary care** **B. Prescribed in secondary care with routine follow-up in primary care** **C. Prescribed in secondary care with routine follow-up in secondary care** **D. Other (please give details):** D. Anito-cel is expected to be prescribed and administered within certified NHS tertiary care centres, consistent with practices for other CAR-T therapies. Ongoing follow-up may remain within tertiary care settings in the short-term before transitioning to secondary care. **For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.** Subsequent treatments and comparators outlined in the draft scope will be provided in secondary care, where patients will also receive routine follow-up appointments. **Would anitocabtagene autoleucel be a candidate for managed access?** Routine access to CAR-T therapies ensure the UK is at the forefront of medical advances. Data from the pivotal iMMagine-1 trial presented at ASH 2025 indicate that both the median PFS and OS had not been reached at the datacut (median follow-up of 15.9 months). In comparison, the long-term (≥5-year) follow-up of the CARTITUDE-1 trial in triple-class exposed multiple myeloma showed that median OS was 60.7	Comments noted. No action is needed.

Section	Consultee/ Commentator	Comments [sic]	Action
		months (95% CI, 41.9 to not estimable) and one third (32/97) of patients remain alive and progression-free after a single infusion of ciltacagtagene autoleucel. On that basis, the inherent clinical uncertainty associated with modelling long-term OS outcomes based on limited follow-up data from the trial can be resolved within the maximum 5-year period of managed access. Therefore, Johnson & Johnson consider that anito-cel to be a suitable candidate for managed access. References: • GILEAD Press release. December 2025. Available at: https://www.gilead.com/news/news-details/2025/kite-announces-new-data-for-pivotal-immagine-1-study-at-ash-2025-highlighting-anito-cels-opportunity-in-relapsed-or-refractory-multiple-myeloma • 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* **43**, 2766-2771(2025). **Do you consider that the use of anitocabtagene autoleucel 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.** The use of a CAR-T such as anito-cel can result in potentially substantial health-related benefits. Anito-cel is thought to be 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	

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		improved quality of life. This benefit of treatment may not be adequately captured in the QALY calculation. References: • 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) **Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics**. No treatments identified for being used differently than advised in their SmPC. [redacted] **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:**	

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		• **could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which anitocabtagene 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 population or recommendations that have a different impact or adverse impact on people with particular disabilities	
	Pfizer	No comment	No action is needed.
Additional comments on the draft scope	Gilead Sciences (Company)	No further comments	No action is needed.
	GlaxoSmithKline	**Under 'related NICE recommendations':** 'Belantamab mafodotin with pomalidomide and dexamethasone for previously treated multiple myeloma' should be moved from 'related technology appraisals in development' to 'related technology appraisals as TAG was published 16 February 2026 [TA1133]	Comments noted. The scope has been updated.

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		'Ciltacabtagene autoleucel for treating relapsed and lenalidomide-refractory multiple myeloma after 1 to 3 therapies [ID4012]' should be added to 'related technology appraisals in development'.	
	Johnson & Johnson Innovative Medicine	No further comments.	No action is needed.
	Pfizer	N/A	No action is needed.

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

- Anthony Nolan
- Takeda