National Institute for Health and Care Excellence

Health Technology Evaluation

Talquetamab for treating relapsed or refractory multiple myeloma after 3 treatments [ID5082]

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 Innovative Medicine	The proposed evaluation route (i.e., STA) is appropriate.	Comment noted, no action required.
	Royal College of Pathologists	The remit and the proposed evaluation route are appropraite	Comment noted, no action required.
Wording	Johnson & Johnson Innovative Medicine	The wording of the remit is appropriate.	Comment noted, no action required.
	Myeloma UK	Myeloma UK considers the remit to reflect the issues of clinical and cost effectiveness.	Comment noted, no action required.

Section	Stakeholder	Comments [sic]	Action
	Royal College of Pathologists	The wording reflects the need to demonstrate clinical effectiveness in a cost effective manner	Comment noted, no action required.
Timing issues	Johnson & Johnson Innovative Medicine	Prior to the recent availability (Q4 2024) of B-cell maturation antigens (BCMA)-targeting antibody therapies (e.g. TA1015, ID4026), patients who received the main three classes of relapsed/refractory multiple myeloma (RRMM) treatments (i.e., anti-CD38 monoclonal antibody (anti-CD38 mAb), a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD) faced a dearth of effective treatment options in the UK. Although BCMA-targeted therapies offer transformative survival benefits for myeloma patients, MM continues to be an incurable and progressive disease. With patient choice being a fundamental aspect of NHS care and services, individuals with triple-class exposed (TCE) RRMM could benefit from additional treatment options after receiving 3 prior lines of therapy, based on their specific circumstances (e.g. risk of infections, etc). This is particularly crucial for TCE RRMM patients who have previously received BCMA-targeted bispecific therapies, and face a reduced life expectancy of 7.4 months[1] as they near the end of their treatment journey. Therefore, despite the recent advancements in treatment, there is a growing unmet clinical/patient need for effective therapies with new mechanism of action, such as talquetamab, to prolong survival and maintain a good quality of life for triple-class exposed RRMM patients, either as an alternative to BCMA-targeted therapies or following disease progression on those treatments. References: **1) Mateos, MV *et al*., P-050 Talquetamab vs Real-World Physician's Choice in Patients With Relapsed/Refractory Multiple Myeloma and Prior B-Cell Maturation Antigen**	Comments noted. NICE has scheduled this topic into its work programme. No action required.

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		Therapy: Analyses of MonumenTAL-1 vs LocoMMotion/MoMMent; Clinical Lymphoma, Myeloma and Leukemia, Volume 24, S69 - S70	
	Royal College of Pathologists	Three is an urgent need for this agent to be evaluated as it appears effective in a very hard ot treat population and may represent a treament approach to improve the quality and duration of life of this patient population,	Comment noted. NICE has scheduled this topic into its work programme. No action required.
Additional comments on the draft remit	Johnson & Johnson Innovative Medicine	No comment	Comment noted, no action required.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Johnson & Johnson Innovative Medicine	No additional comments	Comment noted, no action required.
	GSK	Appendix B states NICE TA658 recommends IsaPomDex within the CDF, but IsaPomDex is now out of the CDF and NICE appraisal ID4067 is the re-appraisal for this triplet. It originally received a non-recommendation and has gone to appeal. The appeal decision was made on 12th November as noted on the NICE website and a few points were upheld and been remitted to the	Comments noted. The background section of the scope is intended to provide a brief introduction to the disease area. Further

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		NICE appraisal committee to address concerns. The information should be updated to reflect these updates. In addition, as per NICE TA1015 and GID-TA10918; Teclistamab and Elrantamab monotherapies should be added to the background information for people who have had at least 3 prior treatments.	information about ID4067 has not been included because the review of TA658 has not yet concluded (final guidance has not yet been published). Teclistamab and elranatamab monotherapies have been added in the background information section for people who have had at least 3 prior treatments.
	Myeloma UK	We consider this information to be sufficient. The statement “The 5-year survival rate for adults with multiple myeloma in England and Wales is estimated to be 52%.” doesn’t reflect the figure reported in the reference. The Cancer Statistic Hub reports the 5-year survival as 55.5% in England and 57.7% in Wales.	Comments noted. The 5-year survival estimates of 55.5% and 57.7% in England and Wales, respectively are age-standardised. The unstandardised 5-year survival rates are 52.3% and 52.2%, respectively. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
	Royal College of Pathologists	The information is accurate and sufficiently complete to perform the scope.	Comment noted, no action required.
Population	Johnson & Johnson Innovative Medicine	No additional comments	Comment noted, no action required.
	Myeloma UK	We consider the population to be appropriately defined. We welcome that it has not been restricted and is in line with the marketing authorisation. 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. It is common in myeloma appraisals that final company submissions are narrower than full marketing authorisation. If the company seeks to pursue 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. The committee will consider unmet need during the development of the appraisal. No action required.

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	Royal College of Pathologists	The population is defined as outlined in EMA approval for this agent	Comment noted, no action required.
Subgroups	Johnson & Johnson Innovative Medicine	Prior T-cell redirection therapy The pivotal clinical trial for talquetamab for this appraisal is MonumenTAL-1, which includes the following cohorts: • Cohort A (0.4mg/kg weekly) • Cohort C (0.8mg/kg every 2 weeks) • Cohort B (0.4mg/kg weekly): this cohort included patients with prior exposure to T-cell redirecting (TCR) therapies. Of note, the majority of patients ([redacted]%) in this cohort were previously exposed to CAR-T1. As CAR-T for RRMM are not currently available for NHS patients, results from this cohort may present some limitations for decision-making. Other Clinical feedback indicates that the majority of patients in UK clinical practice will likely receive the biweekly (Q2W) regimen due to improved convenience over the weekly regimen, however both the weekly and biweekly regimens are permitted per the talquetamab SmPC. Therefore, J&J IM considers the following subgroup analyses as relevant: • Cohort C (0.8mg/kg Q2W): patients not exposed to prior TCR therapies • Pooled cohort of Cohort A (0.4mg/kg weekly) + C (0.8mg/kg Q2W): patients not exposed to prior TCR therapies Prior lines of therapy Given the high unmet need and poor outcomes observed in later lines of multiple myeloma treatment, J&J IM considers that talquetamab should be	Comments noted. If evidence allows the company can present subgroups in their submission for the committee to consider. The committee will consider the relevance of these subgroups in line with NICE's methods outlined in the CHTE 2022 manual. Prior lines of therapy remains as a subgroup for consideration, if the evidence allows, as outcomes may differ depending on previous lines of therapy. No action required.

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		made available to all eligible patients, such that there are no additional subgroups which should be considered separately. References 1) MonumenTAL-1 Data on File, J&J IM	
	Royal College of Pathologists	This will depend upon the previous therapy to which paitents have been exposed and as in previous NICE appraisals this will likely be defined by the appraisal	Comment noted, no action required.
Comparators	Johnson & Johnson Innovative Medicine	J&J IM considers **teclistamab (TA1015)** as the most relevant comparator to talquetamab. Teclistamab was recently recommended by NICE for routine commissioning for treating RRMM in adults, only after 3 or more lines of treatment (including an IMiD, PI, anti-CD38) when the myeloma has progressed on the last treatment. Prior to the recommendation of teclistamab, it was established that '*the main treatment that is used for RRMM myeloma after 3 or more lines of treatment is pomalidomide plus dexamethasone (PomDex). If pomalidomide plus dexamethasone is not suitable, panobinostat plus bortezomib and dexamethasone (PanoBorDex) can be used. If the myeloma is refractory to 5 or more treatments, selinexor plus dexamethasone (SelDex) can be used*.[2]'. Teclistamab significantly improves clinical outcomes for patients compared to PomDex, PanoBorDex and SelDex, and was also accepted as cost-effective against these treatment options[2]. Therefore, teclistamab represents the new standard of care (SoC) for 4L+ TCE RRMM patients, and the most relevant comparator for talquetamab.	Comments noted. Belantamab mafodotin monotherapy has been removed as a comparator because the appraisal has been suspended due to the withdrawal of the 5L+ license. Elranatamab has been removed as a comparator because final guidance was published on 11th December 2024 recommending elranatamab with managed access (not routine commissioning).

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		J&J IM does not consider the following treatments included in the NICE draft scope as relevant comparators: • **PomDex** (TA427), **PanoBorDex** (TA380) and **SelDex (**TA970) are not relevant comparators to talquetamab for 4L+ TCE RRMM patients as they have been displaced by teclistamab as the new SoC for NHS patients with 4L+ TCE RRMM. • **Lenalidomide plus dexamethasone** (TA171) is not a relevant comparator because patients would have received it earlier in therapy as first- (TA587) or second- (TA586) line treatment in this setting. This is further supported by clinical experts in TA505, as well as in comments for the scoping consultation of ID4026, stated that lenalidomide plus dexamethasone is mainly used after 2 prior therapies, and that it can be used for people who had 3 previous therapies, provided that they have not had lenalidomide before. Due to the disease pathophysiology, recycling of existing therapies in RRMM has limited efficacy as patients are re-exposed to treatments or classes of agents that they have previously developed resistance to[3]. As such, given this combination would most likely be used earlier in the pathway, the re-use in this setting would be limited by previous exposure at earlier lines in the pathway. • **Ixazomib plus lenalidomide and dexamethasone** (TA870) is not a relevant comparator. As this combination contains lenalidomide, patients who previously received lenalidomide are not routinely re-challenged in later lines of therapy. Furthermore, ixazomib plus lenalidomide and dexamethasone is mostly used in the 3rd line setting, based on expert clinical opinion. • **Daratumumab monotherapy** (TA783) is recommended in patients with relapsed or refractory multiple myeloma after 3 prior therapies. Patients eligible for talquetamab, however, will have received daratumumab in earlier lines of therapy (for example, daratumumab in	The following treatments have also been removed as comparators based on committee conclusions in the recent NICE appraisals of teclistamab (TA1015) and elranatamab (TA1023): • lenalidomide plus dexamethasone; • ixazomib plus lenalidomide and dexamethasone; • daratumumab monotherapy; • cyclophosphamide plus dexamethasone. Other comparators remain unchanged. The comparators listed in the scope aim to be inclusive. Some comparators are included subject to the outcome of the NICE evaluation (in the event

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		combination with bortezomib and dexamethasone TA897, or daratumumab in combination with lenalidomide and dexamethasone, TA917). As patients are not routinely re-challenged with daratumumab in later lines of therapy, daratumumab monotherapy is not a relevant comparator for patients who have already been exposed to the anti-CD38 mAb in this setting. • **Cyclophosphamide plus dexamethasone or an alternative alkylating chemotherapy** is not standard of care for patients at the 4th line setting, and as such is not a relevant comparator. Clinical insights received indicate that this chemotherapy combination would either be used earlier in the UK treatment pathway, and typically used in combination with a PI, such as bortezomib. Or alternatively, clinical insights suggests that this combination is used as a salvage option due to a lack of effective treatment options • **Isatuximab with pomalidomide and dexamethasone** is not a relevant comparator in this setting. Patients who are eligible for isatuximab with pomalidomide and dexamethasone are those who are not previously refractory to a CD38 mAb, which represent a different cohort of patients to those eligible for teclistamab. Real-world evidence in the UK has confirmed that over 95% of IsaPd patients are anti-CD38 naïve[4]. Further, isatuximab with pomalidomide and dexamethasone is not currently routinely commissioned in the UK (CDF only) as it is currently undergoing the NICE evaluation following an appeal process, and should not be considered a relevant comparator at this time. • **Elranatamab (ID4026)** was recently recommended for a similar indication as talquetamab. However, elranatamab is currently funded via the Cancer Drugs Fund. Therefore, elranatamab does not qualify as established medicine within NHS practice and, thus, should not be considered a relevant comparator at this time.	they become established clinical practice prior to the appraisal of talquetamab by committee). Stakeholders can provide justification around the most appropriate comparators during the appraisal. The appraisal committee will discuss the most appropriate comparator(s). This will depend on the marketing authorisation, the current treatment pathway, the clinical and cost-effectiveness evidence and current clinical practice.

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		• **Belantamab madofotin (monotherapy)** is not a relevant comparator as it is not currently considered a standard treatment currently used in the NHS. The MHRA has made a decision to revoke the conditional marketing authorisation for belantamab mafodotin, resulting in suspension of the NICE appraisal (ID2701). • **Belantamab madofotin with bortezomib and dexamethasone (ID6212)** is not a relevant comparator for talquetamab in this setting at this time, as it is pending NICE guidance. Therefore, it is not currently considered a standard treatment currently used in the NHS and will not be in routine use by the time of the submission. • **Belantamab madofotin with pomalidomide and dexamethasone (ID6211)** is not a relevant comparator for talquetamab in this setting at this time, as it is pending NICE guidance. Therefore, it is not currently considered a standard treatment currently used in the NHS and will not be in routine use by the time of the submission. References: 1) Mateos, MV., Weisel, K., De Stefano, V. et al. LocoMMotion: a prospective, non-interventional, multinational study of real-life current standards of care in patients with relapsed and/or refractory multiple myeloma. Leukemia 2022; 36, 1371–1376 2) Teclistamab NICE Technology appraisal guidance (TAG), p4, 8; https://www.nice.org.uk/guidance/ta1015/resources/teclistamab-for-treating-relapsed-and-refractory-multiple-myeloma-after-3-or-more-treatments-pdf-2973528275441605 3) Kumar SK, Lee JH, Lahuerta JJ, Morgan G, Richardson PG, Crowley J, et al. Risk of progression and survival in multiple myeloma relapsing after therapy with IMiDs and bortezomib: A multicenter international myeloma working group study. Leukemia. 2012 Jan;26(1):149–5 4) Djebbari F et al .Efficacy of Isatuximab With Pomalidomide and Dexamethasone in Relapsed Myeloma: Results of a UK-Wide Real-World Dataset. Hemasphere. 2022 May 26;6(6):e738.	

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	GSK	Appendix B states 'belantamab mafodotin' (subject to NICE evaluation) in the comparators list which appears to relate to belantamab mafodotin monotherapy. This should be removed as the technology has been suspended due to the withdrawal of the 5L+ license. The wording of 'Teclistamab (subject to NICE evaluation)' should be updated as the NICE guidance has been published.	Comments noted. Belantamab mafodotin monotherapy has been removed as a comparator. The text 'subject to NICE evaluation' has been removed in relation to teclistamab.
	Myeloma UK	We agree that the comparators listed are treatments available to patients at fourth line or beyond however they are not all relevant to this appraisal. In clinical practice the treatments people get at fourth line depends on the NICE approval, licenced indication and the treatments they got at earlier lines. Furthermore, teclistamab and elranatamab are no longer subject to a NICE evaluation and have both been approved for use. In current clinical practice it is our understanding that triple-class exposed patients, after at least 3 prior treatments, will receive: • Teclistamab • Elranatamab • Pomalidomide and dexamethasone • Selinexor plus dexamethasone (penta- exposed patients at fifth line only)	Comments noted. The text 'Subject to NICE evaluation' has been removed in relation to teclistamab. Note belantamab mafodotin monotherapy has been removed as a comparator because the appraisal has been suspended due to the withdrawal of the 5L+ license. Elranatamab has also been removed as a comparator because

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		• Cyclophosphamide and dexamethasone OR alternative alkylating chemotherapy and corticosteroid (only used when there are no other options) • Clinical trial • Compassionate use / Early access scheme The combination of panobinostat plus bortezomib and dexamethasone is not widely used in clinical practice. Combinations with lenalidomide are not widely used at fourth line and beyond as majority of patients will have received lenalidomide at previous lines of treatment. Daratumumab monotherapy is not suitable for people with previous exposure to anti-CD38 monoclonal antibodies and therefore can't be considered a comparator.	final guidance was published on 11th December 2024 recommending elranatamab with managed access (not routine commissioning). The following treatments have also been removed as comparators based on committee conclusions in the recent NICE appraisals of teclistamab (TA1015) and elranatamab (TA1023): • lenalidomide plus dexamethasone; • ixazomib plus lenalidomide and dexamethasone; • daratumumab monotherapy; • cyclophosphamide plus dexamethasone.

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			Other comparators remain unchanged. The comparators listed in the scope aim to be inclusive. Stakeholders can provide justification around the most appropriate comparators during the appraisal. The appraisal committee will discuss the most appropriate comparator(s). This will depend on the marketing authorisation, the current treatment pathway, the clinical and cost-effectiveness evidence and current clinical practice.
	Royal College of Pathologists	Yes, the comparators are currently available or likely soon to be available agent	Comment noted. Note belantamab mafodotin monotherapy has been removed as a comparator because the appraisal has been suspended due to the

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			withdrawal of the 5L+ license. Elranatamab has also been removed as a comparator because final guidance was published on 11th December 2024 recommending elranatamab with managed access (not routine commissioning). The following treatments have also been removed as comparators based on committee conclusions in the recent NICE appraisals of teclistamab (TA1015) and elranatamab (TA1023): • lenalidomide plus dexamethasone; • ixazomib plus lenalidomide and dexamethasone;

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			• daratumumab monotherapy; • cyclophosphamide plus dexamethasone. Other comparators remain unchanged.
Outcomes	Johnson & Johnson Innovative Medicine	The outcomes listed are broadly appropriate. In addition to the outcomes considered in the draft scope, J&J IM considers that time to next treatment (TTNT) may also be included.	Comments noted. Time to next treatment has been added as an outcome.
	Myeloma UK	Yes	Comment noted, no action required.
	Royal College of Pathologists	Yes	Comment noted, no action required.
Equality	Johnson & Johnson Innovative Medicine	No equality issues have been identified.	Comment noted, no action required.
	Myeloma UK	We don't anticipate that a positive recommendation would impact people within the patient population for which the treatment is be licensed, who are protected by the equality legislation differently to the wider population.	Comments noted. Implementation of treatment pathways is not an issue that can be addressed by a NICE

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		As with all treatments the costs incurred by hospital visits and time off work will have a more significant impact on people with lower incomes. For bi-specific treatments, like talquetamab, this includes the requirement to stay in or near the hospital for 48 hours after each set-up dose. Implementation plans must ensure all patients have the opportunity to access this treatment.	technology appraisal recommendation. No action required.
	Royal College of Pathologists	Patients from some ethnic subgroups have worse outcome in myeloma and may therefore more quickly come to need for 4L treatment	Comment noted. The committee will consider whether its recommendations could have a different impact on people protected by the equality legislation than on the wider population.
Other considerations	Johnson & Johnson Innovative Medicine	No comments	Comment noted, no action required.
	GSK	Within ‘related technology appraisals in development’; the following is listed; Belantamab mafodotin for treating relapsed or refractory multiple myeloma after 4 or more therapies. NICE technology appraisal guidance [ID2701]. Publication date to be confirmed This should either be removed or updated to ‘Suspended’.	Comment noted. This appraisal has been removed from the section ‘related technology appraisals in development’.

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	Royal College of Pathologists	None	Comment noted, no action required.
Questions for consultation	Johnson & Johnson Innovative Medicine	***Where do you consider talquetamab will fit into the existing care pathway for multiple myeloma?*** J&J considers that talquetamab will fit as an option for patients who have received at least three prior lines of therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. ***Please select from the following, will talquetamab be:*** ***A. Prescribed in primary care with routine follow-up in primary care*** ***B. Prescribed in secondary care with routine follow-up in primary care*** ***C. Prescribed in secondary care with routine follow-up in secondary care*** ***D. Other (please give details):*** ***For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention***. As the comparator, teclistamab is prescribed in secondary care with routine follow-up in secondary care. Subsequent treatments are likewise prescribed in secondary care with routine follow-up in secondary care. ***Would talquetamab be a candidate for managed access?***	Comments noted, The committee will discuss if all benefits of talquetamab were captured in the cost-effectiveness analyses during the appraisal. No action required.

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		J&J IM is [redacted]. ***Do you consider that the use of talquetamab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation*** J&J IM considers that talquetamab, as a first-in-class bispecific monotherapy treatment, works in a completely different way to the myeloma drugs routinely commissioned for use in the UK. Talquetamab binds to the CD3 receptor expressed on the surface of T-cells and G protein-coupled receptor class C group 5 member D (GPRC5D), a novel multiple myeloma target which is highly expressed on the surface of multiple myeloma cells and non-malignant plasma cells, as well as some healthy tissues such as epithelial cells of the skin and tongue. The benefit of an additional treatment option with a novel mechanism of action for patients at this stage of the disease pathway, in particular prior TCR therapy-exposed patients, may not be captured in the QALY framework. A diagnosis of MM also has a substantial psychological impact, with patients living in fear of relapse. **Improvements in mental health, reduced anxiety, and enhanced quality of life** due to a new treatment option also may not be fully accounted for in QALY calculations. Additional psychological benefits from talquetamab, such as prolonged remission and reduction in anxiety associated with relapse, are aligned to MM patient preferences and are not explicitly considered in the QALY framework. Talquetamab has been shown to result in clinically significant improvements in global health status (GHS), physical functioning and reductions in fatigue	

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		and pain in both the QW and Q2W cohorts[1]. In addition, an increasing ability to engage in social roles and activities was reported in the QW cohort and emotional functioning in the Q2W cohort. Patients' global impression of their MM disease severity (PGIS) also improved from baseline. Patients also reported improvements in their health status (EQ-5D-5L VAS score). ***Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits*** EORTC QLQ-C30 data relating to Symptoms, functioning and health-related quality of life in patients treated with talquetamab**.** References: **1) Carolina Schinke, Cyrille Touzeau, Albert Oriol. Symptoms, Functioning, and Health-Related Quality of Life in Patients with Relapsed/Refractory Multiple Myeloma Treated with Talquetamab: Updated Patient-Reported Outcomes from the Phase 1/2 MonumenTAL-1 Study. *Blood* 2023; 142 (Supplement 1): 6711.**	
	Myeloma UK	• *Where do you consider talquetamab will fit into the existing care pathway for multiple myeloma?* We believe talquetamab will be used within the full scope of it's market authorisation. Myeloma is a very heterogenous cancer which has a dynamic and evolving pathway. The sequencing of treatments depends on previous treatment, patient preference and overall health and fitness. • *Would talquetamab be a candidate for managed access?* Yes. The current market authorisation is a conditional approval and clinical trials are ongoing.	Comments noted, The committee will discuss if all benefits of talquetamab were captured in the cost-effectiveness analyses during the appraisal. No action required.

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		• *Do you consider that the use of talquetamab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?* Talquetamab is a new type of myeloma drug. It works in a completely different way to the myeloma drugs routinely commissioned for use in the UK. As a GPRC5D targeted T-cell engager it would introduce a novel treatment approach into the pathway. As well as giving refractory patients hope, it also gives patients who may have never experienced complete response or lengthy remissions an opportunity to do so. Talquetamab is a monotherapy and therefore not given in combination with dexamethasone like many available treatments. Steroids can cause mood swings, aggression, fatigue, insomnia and other complications. This is difficult for patients and their families to live with.	
	Royal College of Pathologists	Already covered	Comment noted, no action required.
Additional comments on the draft scope	Royal College of Pathologists	The draft scope is appropriate and timely The treatment of myeloma is evolving rapidly with many new treatments available and when patients relapse they will had had different first line therapy dependent upon when and how they were treated (under NICE guidance or in clinical trial) and how long they remained in remission before need for second line therapy. Talquetamab is certainly an effective treatment based upon the results of clinical trials and is FDA and EMA approved for use in myeloma in patients who have received a proteosome inhibitor, an immunomodulatory agent and	Comment noted. NICE has scheduled this topic into its work programme. No action required.

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		an anti-CD38 monoclonal antibody and this is the scope being evaluated here and is therefore appropriate.	

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

Takeda