NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Anitocabtagene autoleucel for treating relapsed or refractory multiple myeloma ID6549

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of anitocabtagene autoleucel within its marketing authorisation for treating relapsed or refractory multiple myeloma.

Background

Multiple myeloma is a cancer of plasma cells, a type of white blood cell, that arises in the bone marrow. Myeloma cells produce large quantities of an abnormal antibody, known as paraprotein. Unlike normal antibodies, paraprotein has no useful function and cannot fight infection. Myeloma cells suppress the development of normal blood cells responsible for fighting infection (white blood cells), carrying oxygen around the body (red blood cells) and blood clotting (platelets). The term multiple myeloma refers to the presence of more than one site of affected bone at the time of diagnosis. People with multiple myeloma can experience bone pain, fractures, tiredness (due to anaemia), infections, hypercalcaemia (high calcium levels in the blood) and kidney problems.

In 2023, 5,706 people were diagnosed with multiple myeloma in England.[1] Incidence increases with age and is highest among people aged 85 to 89 years, accounting for around 1 in 10 (9%) of all new cases diagnosed in the UK (2017-2019).[2] In England, the estimated 5-year net survival rate from diagnosis for adults is 55.5% (2016-2020).[3] Multiple myeloma is more common in men than in women.[1] Incidence rates are reported to be higher in people from Black ethnic groups, lower in people from Asian ethnic groups, and similar in people of mixed or multiple ethnicity, compared with the White ethnic group in England (2013-2017).[2]

The main aims of treatment are to prolong survival and maintain quality of life by controlling the condition and relieving symptoms. If the condition progresses after initial treatment, the choice of subsequent treatment is influenced by previous treatment and response, duration of remission, comorbidities and patient preference.

For people who have had at least 1 prior treatment:

- NICE technology appraisal 129 recommends bortezomib monotherapy, although this treatment is rarely used in NHS clinical practice.
- NICE technology appraisal 586 recommends lenalidomide plus dexamethasone after 1 line of treatment containing bortezomib.
- NICE technology appraisal 657 recommends carfilzomib plus dexamethasone.

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- NICE technology appraisal 695 recommends carfilzomib plus lenalidomide and dexamethasone, after 1 line of treatment containing bortezomib.

- NICE technology appraisal 897 recommends daratumumab plus bortezomib and dexamethasone after 1 line of treatment that included lenalidomide, or if lenalidomide is unsuitable at second line.

- NICE technology appraisal 974 recommends selinexor plus bortezomib and dexamethasone after 1 line of treatment and the condition is refractory to both daratumumab and lenalidomide.

For people who have had at least 2 prior treatments:

- NICE technology appraisal 171 recommends lenalidomide plus dexamethasone after 2 or more lines of treatment.

- NICE technology appraisal 380 recommends panobinostat plus bortezomib and dexamethasone after 2 or more lines of treatment including bortezomib and an immunomodulatory agent.

- NICE technology appraisal guidance 870 recommends ixazomib plus lenalidomide and dexamethasone after 2 or 3 lines of treatment.

- NICE also recommends selinexor plus bortezomib and dexamethasone if the condition is refractory to lenalidomide (TA974).

For people who have had at least 3 prior treatments:

- NICE technology appraisal guidance 427 recommends pomalidomide plus low-dose dexamethasone after at least 3 lines of treatment including both lenalidomide and bortezomib.

- NICE technology appraisal guidance 783 recommends daratumumab monotherapy after at least 3 lines of treatment including a proteasome inhibitor and an immunomodulator.

- NICE technology appraisal guidance 1015 recommends teclistamab monotherapy after at least 3 lines of treatment including an immunomodulator, a proteasome inhibitor and an anti-CD38 antibody.

- NICE technology appraisal guidance 1114 recommends talquetamab after at least 3 lines of treatment including an immunomodulatory drug, a proteasome inhibitor, and an anti-CD38 antibody, and the myeloma had progressed on the last treatment.

- NICE also recommends lenalidomide plus dexamethasone (TA171), panobinostat plus bortezomib and dexamethasone (TA380), and ixazomib plus lenalidomide and dexamethasone (TA870).

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In addition, NICE recommends the following technologies within the Cancer Drugs Fund:

- elranatamab monotherapy after at least 3 lines of treatment including an immunomodulator, a proteasome inhibitor and an anti-CD38 antibody (NICE technology appraisal guidance 1023).

- isatuximab plus pomalidomide and dexamethasone after at least 3 lines of treatment including lenalidomide and a proteosome inhibitor (TA658; NICE technology appraisal guidance ID4067).

For people who have had at least 4 prior treatments:

- NICE technology appraisal guidance 970 recommends selinexor plus dexamethasone after at least 4 lines of treatment including 2 proteasome inhibitors, 2 immunomodulatory agents and an anti-CD38 monoclonal antibody.

- NICE also recommends panobinostat plus bortezomib and dexamethasone (TA380), pomalidomide plus low-dose dexamethasone (TA427), teclistamab monotherapy (TA1015) and talquetamab (TA1114) under routine commissioning, and elranatamab monotherapy within the Cancer Drugs Fund (TA1023).

The technology

Anitocabtagene autoleucel (brand name unknown, Arcellx and Kite, Gilead Sciences) does not currently have a marketing authorisation in the UK for relapsed or remitting multiple myeloma. It has been studied in clinical trials in which anitocabtagene autoleucel regimens were compared with standard of care in people with multiple myeloma who had 1 to 3 lines of prior treatment.

Intervention(s)	Anitocabtagene autoleucel
Population(s)	People with relapsing or remitting multiple myeloma
Subgroups	If the evidence allows the following subgroups will be considered: • Prior lines of treatment

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Comparators	Depending on previous lines of treatment, comparators can include: • bortezomib monotherapy • carfilzomib plus dexamethasone • carfilzomib plus lenalidomide and dexamethasone • daratumumab monotherapy • daratumumab plus bortezomib and dexamethasone • ixazomib plus lenalidomide and dexamethasone • lenalidomide plus dexamethasone • panobinostat plus bortezomib and dexamethasone • pomalidomide plus low-dose dexamethasone • selinexor plus bortezomib and dexamethasone • selinexor plus dexamethasone • talquetamab • teclistamab monotherapy • belantamab mafodotin plus bortezomib and dexamethasone (subject to NICE evaluation) • belantamab mafodotin plus pomalidomide and dexamethasone (subject to NICE evaluation) • isatuximab plus pomalidomide and dexamethasone (subject to NICE evaluation) • mezigdomide plus dexamethasone and carfilzomib (subject to NICE evaluation) • teclistamab plus daratumumab (subject to NICE evaluation)
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • response rates • adverse effects of treatment • health-related quality of life.

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Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. 'The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability and cost of biosimilar and generic products should be taken into account.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations	**Related technology appraisals:** Talquetamab for treating relapsed and refractory multiple myeloma after 3 or more treatments (2025) NICE technology appraisal guidance 1114. Elranatamab for treating relapsed and refractory multiple myeloma after 3 or more treatments (2024) NICE technology appraisal guidance 1023. Teclistamab for treating relapsed and refractory multiple myeloma after 3 or more treatments (2024) NICE technology appraisal guidance 1015. Selinexor with dexamethasone for treating relapsed and refractory multiple myeloma after 4 or more treatments (2024) NICE technology appraisal guidance 970. Ixazomib with lenalidomide and dexamethasone for treating relapsed or refractory multiple myeloma (2023) NICE technology appraisal guidance 870. Daratumumab monotherapy for treating relapsed and refractory multiple myeloma (2022) NICE technology appraisal guidance 783. Pomalidomide for multiple myeloma previously treated with lenalidomide and bortezomib (2017) NICE technology appraisal guidance 427.

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	Panobinostat for treating multiple myeloma after at least 2 previous treatments (2016) NICE technology appraisal guidance 380. Lenalidomide for the treatment of multiple myeloma in people who have received at least 2 prior therapies (2009, updated 2019) NICE technology appraisal guidance 171. **Related technology appraisals in development:** Belantamab mafodotin with pomalidomide and dexamethasone for previously treated multiple myeloma NICE technology appraisal guidance [ID6211] Publication expected February 2026. Isatuximab with pomalidomide and dexamethasone for treating relapsed and refractory multiple myeloma [review of TA658] NICE technology appraisal guidance [ID4067] Publication expected March 2026. Belantamab mafodotin with bortezomib and dexamethasone for treating relapsed or refractory multiple myeloma after 1 or more treatments NICE technology appraisal guidance [ID6212] Publication expected April 2026. Teclistamab with daratumumab for treating relapsed or refractory multiple myeloma after 1 or more therapies NICE technology appraisal guidance [ID6201] Publication expected July 2027. Mezigdomide with dexamethasone and carfilzomib for treating relapsed or refractory multiple myeloma after at least 1 line of treatment NICE technology appraisal guidance [ID6513] Publication date to be confirmed. Elranatamab for treating relapsed or refractory multiple myeloma after 2 treatments NICE technology appraisal guidance [ID6464] Publication date to be confirmed. Elranatamab for treating relapsed or refractory multiple myeloma after treatments including anti-CD38 antibody and lenalidomide therapy NICE technology appraisal guidance [ID6591] Publication date to be confirmed. Linvoseltamab for treating relapsed or refractory multiple myeloma after 3 or more treatments NICE technology appraisal guidance [ID6609] Publication date to be confirmed. Talquetamab with daratumumab for treating relapsed or refractory multiple myeloma after 1 or more lines of treatment including a proteasome inhibitor and lenalidomide NICE technology appraisal guidance [ID6625] Publication date to be confirmed. Talquetamab with pomalidomide or teclistamab for treating relapsed or refractory multiple myeloma after 1 or more treatments including an anti-CD38 antibody and lenalidomide NICE technology appraisal guidance [ID6629] Publication date to be confirmed.

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	Teclistamab for treating relapsed or refractory multiple myeloma after 1 or more treatments including an anti-CD38 antibody and lenalidomide NICE technology appraisal guidance [ID6628] Publication date to be confirmed. **Related NICE guidelines:** Myeloma: diagnosis and management (2016; updated October 2018) NICE guideline NG35. **Related quality standards:** Haematological cancers (2017) NICE quality standard 150.

Questions for consultation

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):
For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would anitocabtagene autoleucel 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?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

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.

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 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;

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- 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.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

References

1. NHS Digital (2025) Cancer Registration Statistics, England, 2023. Accessed February 2026.

2. Cancer Research UK (2025) Myeloma statistics. Accesssed February 2026.

3. NHS Digital (2023) Cancer Survival in England, cancers diagnosed 2016 to 2020, followed up to 2021. Accessed February 2026.

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