NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Brexucabtagene autoleucel for treating relapsed or refractory mantle cell lymphoma after 2 or more systemic treatments [ID6325]

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of brexucabtagene autoleucel within its marketing authorisation for treating relapsed or refractory mantle cell lymphoma after 2 or more systemic treatments.

Background

Lymphomas are cancers of the lymphatic system, which is a part of the immune system. Lymphomas are divided into Hodgkin lymphoma and non-Hodgkin lymphoma. Non-Hodgkin lymphomas (NHL) are a diverse group of conditions which are categorised according to the cell type affected (B-cell or T-cell), as well as the clinical features and rate of progression of the disease. Mantle cell lymphoma is a rare and often aggressive type of NHL which affects B-cells.

There were 543 new cases of mantle cell lymphoma diagnosed in England in 2021.[1] Regional data from the north-east of England indicates that the 5-year survival rate for people with mantle cell lymphoma is 47.4%, and the median age at diagnosis is around 72 years.[2] Mantle cell lymphoma is more common in men than women (3:1 ratio).[3]

NICE technology appraisal 370 recommends bortezomib for previously untreated mantle cell lymphoma. First-line treatment of mantle cell lymphoma may also include rituximab chemotherapy, and allogeneic haemopoietic stem-cell transplantation for fitter patients. Allogeneic haemopoietic stem-cell transplantation is a potentially curative treatment in patients for whom it is suitable. NICE technology appraisal 502 recommends ibrutinib as an option for treating relapsed or refractory mantle cell lymphoma in adults, if they have had only 1 previous line of therapy. There is no accepted standard of care for treating relapsed or refractory mantle cell lymphoma in people who have received at least 2 previous lines of therapy. A range of chemotherapy regimens with rituximab are used such as, RBAC (rituximab, bendamustine and cytarabine), rituximab plus bendamustine, RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisolone), RCVP (rituximab, cyclophosphamide, vincristine, and prednisolone) and single-agent cytarabine.

The technology

Brexucabtagene autoleucel (Tecartus, Gilead Sciences Ltd) has marketing authorisation in the UK for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after 2 or more lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor.

Intervention	Brexucabtagene autoleucel
Population	People with relapsed or refractory mantle cell lymphoma who have had at least 2 previous lines of therapy including a Bruton's tyrosine kinase (BTK) inhibitor
Comparators	Established clinical management including but not limited to: • Chemotherapy with or without rituximab • Zanubrutinib (subject to NICE evaluation) • Allogeneic haemopoietic stem cell transplant
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • response rate • adverse effects of treatment • health-related quality of life.
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:** Ibrutinib for treating relapsed or refractory mantle cell lymphoma (2018). NICE Technology Appraisal 502.

	Temsirolimus for the treatment of relapsed or refractory mantle cell lymphoma (terminated appraisal) (2010). NICE Technology Appraisal 207. Lenalidomide for relapsed or refractory mantle cell lymphoma (terminated appraisal) (2022). NICE Technology Appraisal 774. Bortezomib for previously untreated mantle cell lymphoma (2015). NICE Technology Appraisal 370. **Related technology appraisals in development:** Zanubrutinib for treating relapsed or refractory mantle cell lymphoma after 1 or more treatments. NICE technology appraisal guidance [ID6392]. Publication date to be confirmed. **Related NICE guidelines:** 'Haematological cancers: improving outcomes' (2016). NICE guideline 47. Review date to be confirmed. 'Non-Hodgkin's lymphoma: diagnosis and management' (2016). NICE guideline 52. Review date to be confirmed. Non-Hodgkin's lymphoma: rituximab subcutaneous injection (2014) NICE evidence summary of new medicines 46. **Related quality standards:** Haematological cancers (2017) NICE quality standard 150
Related National Policy	NHS England (2018) Clinical Commissioning Policy: Bortezomib for relapsed/refractory mantle cell lymphoma (all ages). NHS England (2018) Clinical Commissioning Policy: Bendamustine with rituximab for first line treatment of mantle cell lymphoma (all ages). NHS England (2018) Clinical Commissioning Policy: Bendamustine with rituximab for relapsed and refractory mantle cell lymphoma (all ages). The NHS Long Term Plan (2019) NHS Long Term Plan NHS England (2023) Manual for prescribed specialist services (2023/2024) See: Chapter 29: Haematopoietic stem cell transplantation services (adults and children) and chapter 105: Specialist cancer services (adults).

Questions for consultation

Where do you consider brexucabtagene autoleucel will fit into the existing care pathway for relapsed or refractory mantle cell lymphoma?

Please select from the following, will brexucabtagene 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.

Is the treatment pathway for mantle cell lymphoma outlined in the background section of this scope accurate?

Have all relevant comparators for brexucabtagene autoleucel been included?

Do you consider that the use of brexucabtagene 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.

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 brexucabtagene autoleucel is 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.

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. Office for National Statistics, 2024. Accessed September 2024.
2. Haematological Malignancy Research Network, 2024. Accessed September 2024
3. M. Dreyling, E. Campo, O. Hermine, M. Jerkeman, S. Le Gouill, S. Rule, O. Shpilberg, J. Walewski, M. Ladetto, on behalf of the ESMO Guidelines

Committee; Newly diagnosed and relapsed mantle cell lymphoma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up, Annals of Oncology, Volume 28, Issue suppl_4, 1 July 2017, Pages iv62–iv71