

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

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

Final scope

Remit/evaluation objective

To appraise the clinical and cost effectiveness of brexucabtagene autoleucl within its marketing authorisation for the treatment of adult patients with relapsed or refractory mantle cell lymphoma after 2 or more systemic treatments including a Bruton's tyrosine kinase inhibitor.

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 In England each year there are around 90 patients with mantle cell lymphoma who relapse or are refractory to 2 or more lines of systemic therapy.

NICE [technology appraisal 370](#) recommends bortezomib for previously untreated mantle cell lymphoma. First-line treatment of mantle cell lymphoma may also include rituximab chemotherapy. Some people who are well enough may receive a first-line induction regimen containing rituximab and high-dose cytarabine. Those who respond to this induction therapy may be offered consolidation autologous stem-cell transplantation. 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. Chemotherapy regimens with rituximab are offered to people who have had 2 or more previous lines of therapy, 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. Some people who are well enough may be offered allogenic stem cell transplantation after 1 or more previous lines of therapy.

The technology

Brexucabtagene autoleucl (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 autoleucl
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: <ul style="list-style-type: none"> • Chemotherapy with or without rituximab • Zanubrutinib (subject to NICE evaluation) • Allogeneic haemopoietic stem cell transplant
Outcomes	The outcome measures to be considered include: <ul style="list-style-type: none"> • overall survival • progression-free survival • response rate • adverse effects of treatment • health-related quality of life.
Economic analysis	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>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.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>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.</p>
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:

	<p>Ibrutinib for treating relapsed or refractory mantle cell lymphoma (2018). NICE Technology Appraisal 502.</p> <p>Temsirrolimus for the treatment of relapsed or refractory mantle cell lymphoma (terminated appraisal) (2010). NICE Technology Appraisal 207.</p> <p>Lenalidomide for relapsed or refractory mantle cell lymphoma (terminated appraisal) (2022). NICE Technology Appraisal 774.</p> <p>Bortezomib for previously untreated mantle cell lymphoma (2015). NICE Technology Appraisal 370.</p> <p>Related technology appraisals in development:</p> <p>Zanubrutinib for treating relapsed or refractory mantle cell lymphoma after 1 or more treatments. NICE technology appraisal guidance [ID6392]. Publication date to be confirmed.</p> <p>Related NICE guidelines:</p> <p>‘Haematological cancers: improving outcomes’ (2016). NICE guideline 47. Review date to be confirmed.</p> <p>‘Non-Hodgkin’s lymphoma: diagnosis and management’ (2016). NICE guideline 52. Review date to be confirmed.</p> <p>Non-Hodgkin’s lymphoma: rituximab subcutaneous injection (2014) NICE evidence summary of new medicines 46.</p> <p>Related quality standards:</p> <p>Haematological cancers (2017) NICE quality standard 150</p>
Related National Policy	<p>NHS England (2018) Clinical Commissioning Policy: Bortezomib for relapsed/refractory mantle cell lymphoma (all ages).</p> <p>NHS England (2018) Clinical Commissioning Policy: Bendamustine with rituximab for first line treatment of mantle cell lymphoma (all ages).</p> <p>NHS England (2018) Clinical Commissioning Policy: Bendamustine with rituximab for relapsed and refractory mantle cell lymphoma (all ages).</p> <p>The NHS Long Term Plan (2019) NHS Long Term Plan</p> <p>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).</p>

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