NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Sonrotoclax for treating relapsed or refractory mantle cell lymphoma after an anti-CD20 treatment and a BTK inhibitor ID6654

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of sonrotoclax within its marketing authorisation for treating relapsed or refractory mantle cell lymphoma after an anti-CD20 treatment and a BTK 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.

There is no accepted standard of care for treating relapsed or refractory mantle cell lymphoma in people who have received prior treatment with an anti-CD20 treatment and a BTK inhibitor. A range of chemotherapy regimens are used such as, R-BAC (rituximab, bendamustine and cytarabine), rituximab plus bendamustine, R-CHOP, (rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisolone), R-CVP (rituximab, cyclophosphamide, vincristine, and prednisolone) and single-agent cytarabine. NICE technology appraisal 677 recommends brexucabtagene autoleucel, in the Cancer Drugs Fund, as an option for treating relapsed or refractory mantle cell lymphoma in adults who have previously had a Bruton's tyrosine kinase (BTK) inhibitor. Some people who are well enough may be offered allogenic stem cell transplantation after 1 or more previous lines of therapy.

The technology

Sonrotoclax (Brand name unknown, BeOne Medicines) does not currently have a marketing authorisation in the UK for relapsed or refractory mantle cell lymphoma. It is being studied in a phase 2 open label, dose escalation trial in people with haematological malignancies and a phase 2 single arm open label trial in people with relapsed or refractory mantle cell lymphoma.

Intervention(s)	Sonrotoclax
Population(s)	People with relapsed or refractory mantle cell lymphoma who have had an anti-CD20 treatment and a BTK inhibitor
Comparators	Established clinical management including but not limited to: • Brexucabtagene autoleucel (subject to NICE evaluation) • Chemotherapy with or without rituximab • Allogenic 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:** Brexucabtagene autoleucel for treating relapsed or refractory mantle cell lymphoma (2021). NICE Technology Appraisal 677.

	Related technology appraisals in development: Brexucabtagene autoleucel for treating relapsed or refractory mantle cell lymphoma after 2 or more systemic treatments (review of TA667) [ID6325]. **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.

Questions for consultation

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

Do you consider allogeneic haemopoietic stem cell transplant to be a relevant comparator for treating relapsed or refractory mantle cell lymphoma after an anti CD20 treatment and a BTK inhibitor?

Please select from the following, will sonrotoclax 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 sonrotoclax be a candidate for managed access?

Do you consider that the use of sonrotoclax 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 sonrotoclax 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.

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. Cancer Registration Statistics, England, 2017. Office of National Statistics. Accessed January 2026

2. Haematological Malignancy Research Network. Accessed January 2026