NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Epcoritamab for treating relapsed or refractory follicular lymphoma ID6338

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of epcoritamab within its marketing authorisation for relapsed or refractory follicular lymphoma.

Background

Lymphomas are cancers of the lymphatic system, which is a part of the immune system. Lymphomas are divided into Hodgkin and non-Hodgkin lymphomas. Non-Hodgkin lymphomas (NHL) are a diverse group of conditions categorised according to the cell type affected (B-cell or T-cell), as well as the clinical features and rate of progression of disease.[1]

Follicular lymphoma is a type of indolent, low-grade lymphoma, meaning they are slow growing, which affects B-lymphocytes. People with this condition typically present with painless lumps (enlarged lymph nodes) in the neck, armpit or groin although there may be additional symptoms such as night sweats and recurrent fevers in some people.[2]

Follicular lymphomas are commonly staged from I (best prognosis) to IV (worse prognosis) and the staging depends on how many groups of lymph nodes are affected, where they are in the body, the size of the areas of lymphoma and whether other organs outside of the lymphatic system such as the bone marrow or liver are affected.[3]

In England in 2022 there were 2,404diagnoses of follicular lymphoma.[4] The 5-year survival rate for those diagnosed with follicular lymphoma is around 90%.[5] Duration of response to chemoimmunotherapy and survival decreases with each subsequent relapse of follicular lymphoma.[6]

People whose disease does not respond to treatment, or relapses after treatment is completed, will usually receive a different combination chemotherapy regimen, with or without rituximab:

- NICE technology appraisal 137 recommends rituximab either alone or in combination with chemotherapy as a treatment option for people with relapsed or refractory stage III or IV follicular NHL.

- NICE technology appraisal 627 recommends lenalidomide with rituximab as an option for previously treated follicular lymphoma (grade 1 to 3A) in adults.

- NICE technology appraisal 629 recommends obinutuzumab with bendamustine followed by obinutuzumab maintenance monotherapy as an option for treating follicular lymphoma that did not respond or progressed up to 6 months after treatment with rituximab or a rituximab-containing regimen.

- Consolidation with autologous or allogeneic stem cell transplantation can also be offered for people with follicular lymphoma, in second or subsequent remission (complete or partial), who meet the eligibility criteria.

The technology

Epcoritamab (Tepkinly, AbbVie) does not currently have a marketing authorisation in the UK for treating relapsed or refractory follicular lymphoma. It has been studied in phase 1/2 open-label clinical studies in people with relapsed, progressive or refractory B-cell lymphoma, including follicular lymphoma. Epcoritamab has a marketing authorisation, as monotherapy, for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy.

Intervention	Epcoritamab
Population	Adults with relapsed or refractory follicular lymphoma
Comparators	Established clinical management without epcoritamab. Treatment choice will depend on previous treatments, and how effective those treatments were. • Lenalidomide with rituximab • Lisocabtagene maraleucel (subject to NICE evaluation) • Obinutuzumab with bendamustine followed by obinutuzumab maintenance • Rituximab monotherapy • Rituximab with chemotherapy • Best supportive care
Outcomes	The outcome measures to be considered include: • Overall survival • Progression-free survival • Response rates • 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:** Axicabtagene ciloleucel for treating relapsed or refractory follicular lymphoma (2023) NICE technology appraisal guidance 894. Mosunetuzumab for treating relapsed or refractory follicular lymphoma (2023) NICE technology appraisal guidance 892. Obinutuzumab with bendamustine for treating follicular lymphoma after rituximab (2020) NICE technology appraisal guidance 629. Lenalidomide with rituximab for previously treated follicular lymphoma (2020) NICE guideline 627. Idelalisib for treating refractory follicular lymphoma (2019) NICE technology appraisal guidance 604. Rituximab for the treatment of relapsed or refractory stage III or IV follicular non-Hodgkin's lymphoma (2008) NICE guideline 137. **Related technology appraisals in development:** Lisocabtagene maraleucel for treating relapsed or refractory large B-cell lymphomas after first-line chemotherapy when a stem cell transplant is suitable. NICE technology appraisal guidance [ID3887] Publication expected December 2024. **Related NICE guidelines:** Non-Hodgkin's lymphoma: diagnosis and management (2016) NICE guideline 52. Haematological cancers: improving outcomes (2016). NICE Guideline 47. 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 (2019) The NHS long term plan NHS England (2023) Manual for prescribed specialised services Chapter 105. Specialist cancer services (adults)

Questions for consultation

Where do you consider epcoritamab will fit into the existing care pathway for relapsed or refractory follicular lymphoma?

Please select from the following, will epcoritamab 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.

Are all the listed comparators appropriate comparators, such as obinutuzumab with bendamustine followed by obinutuzumab maintenance and rituximab monotherapy?

Should any subgroups be considered?

Would epcoritamab be a candidate for managed access?

Do you consider that the use of epcoritamab 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 epcoritamab 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. Cancer Research UK. How doctors group non-Hodgkin lymphomas. Accessed October 2024.

2. Cancer Research UK. Symptoms. Accessed October 2024.

3. Cancer Research UK. Stages of non-Hodgkin lymphoma. Accessed October 2024.

4. NHS Digital. Cancer Registrations Statistics, England 2022- First release, counts only. Accessed October 2024.

5. Cancer Research UK. Survival. Accessed October 2024.

6. Rivas-Delgado A, Magnano L, Moreno-Velázquez M et al. Response duration and survival shorten after each relapse in patients with follicular lymphoma treated in the rituximab era. British Journal of Haematology. 2018;184(5):753-759.