

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Mosunetuzumab for treating relapsed or refractory follicular lymphoma
[ID3931]

Final scope

Final remit/appraisal objective

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

Background

Lymphomas are cancers of the lymphatic system, which is part of the immune system and are divided into Hodgkin and non-Hodgkin lymphomas. Non-Hodgkin lymphomas are a diverse group of conditions which can affect either of the 2 main types of lymphocytes, T lymphocytes or B lymphocytes. Non-Hodgkin lymphomas can be low grade, or indolent, meaning they are slow growing, or high-grade, meaning they grow faster and more aggressively.¹

Follicular lymphoma is a type of indolent, low grade lymphoma 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 2018 there were 11,944 diagnoses of non-Hodgkin's lymphoma and 2329 (19%) of those were 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

Clinical management for relapsed and refractory follicular lymphoma includes:

- [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 non-Hodgkin's lymphoma.
- [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.
- [NICE technology appraisal 627](#) recommends lenalidomide with rituximab as an option for previously treated follicular lymphoma (grade 1 to 3A) in adults.

Final scope for the appraisal of mosunetuzumab for treating relapsed or refractory follicular lymphoma

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Page 1 of 4

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- Consolidation with autologous or allogenic 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

Mosunetuzumab (brand name unknown, Roche) is a bispecific fully humanised monoclonal antibody that has 2 distinct “Fab” regions, meaning that the antibody can bind 2 distinct targets. One of these regions is specific for CD20, which is expressed in the majority of B-cell malignancies, and the other is specific for CD3 which is a receptor on T-lymphocytes. By binding both cells the antibody mediates activation of the recruited T-lymphocytes against the CD20 expressing B-cells, resulting in B-cell death and an anti-tumour effect.

Mosunetuzumab does not currently have a marketing authorisation in the UK but is being assessed as both a monotherapy and in combination with atezolizumab in a single arm clinical trial of adults with relapsed or refractory non-Hodgkin’s lymphoma, including a subset of patients with follicular lymphoma, or chronic lymphocytic leukaemia after at least 1 prior treatment. It is administered intravenously.

Intervention(s)	Mosunetuzumab
Population(s)	Adults with relapsed or refractory follicular lymphoma
Comparators	<p>Established clinical management without mosunetuzumab. Treatment choice will depend on previous treatments, and how effective those treatments were.</p> <ul style="list-style-type: none"> • Obinutuzumab with bendamustine followed by obinutuzumab maintenance • Lenalidomide with rituximab • Rituximab in combination with chemotherapy • Best supportive care
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • Overall survival • Progression free survival • Response rates • 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.</p> <p>The availability and cost of biosimilar and generic products should be taken into account.</p>
Other considerations	<p>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.</p>
Related NICE recommendations and NICE Pathways	<p>Related Technology Appraisals:</p> <p>Rituximab for the treatment of relapsed or refractory stage III or IV follicular non-Hodgkin's lymphoma (2008). NICE technology appraisal guidance 137. Guidance moved to static list.</p> <p>Idelalisib for treating refractory follicular lymphoma (2019). NICE technology appraisal guidance 604. Review date 2022.</p> <p>Lenalidomide with rituximab for previously treated follicular lymphoma (2020). NICE technology appraisal guidance 627. Review date 2023.</p> <p>Obinutuzumab with bendamustine for treating follicular lymphoma after rituximab (2020). NICE technology appraisal guidance 629. Review date 2023.</p> <p>Terminated appraisals:</p> <p>Bendamustine for the treatment of indolent (low grade) non-Hodgkin's lymphoma that is refractory to rituximab NICE technology appraisal guidance 206</p> <p>Duvelisib for treating relapsed follicular lymphoma after 2 or more systemic therapies NICE technology appraisal guidance 717</p> <p>Appraisals in development (including suspended appraisals):</p> <p>Ibrutinib for treating relapsed or refractory follicular lymphoma NICE technology appraisal guidance [ID1251]. Publication</p>

	<p>date to be confirmed.</p> <p>Bortezomib for the treatment of relapsed or refractory follicular non-Hodgkin's lymphoma NICE technology appraisal guidance [ID407]. Suspended March 2012.</p> <p>Ofatumumab (Arzerra) in combination with chemotherapy for follicular lymphoma; second line - refractory to rituximab NICE technology appraisal guidance [ID1487]. Suspended November 2018.</p> <p>Tisagenlecleucel for treating follicular lymphoma after 2 or more therapies Proposed NICE technology appraisal guidance [ID3950]. Publication date to be confirmed.</p> <p>Related Guidelines:</p> <p>Non-Hodgkin's lymphoma: diagnosis and management (2016) NICE guideline 52</p> <p>Haematological cancers: improving outcomes (2016) NICE guideline 47</p> <p>Related Quality Standards:</p> <p>Haematological cancers (2017) NICE quality standard 150</p>
<p>Related National Policy</p>	<p>The NHS Long Term Plan, 2019. NHS Long Term Plan</p> <p>NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019) Chapter 105</p> <p>Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domains 1-5 https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017</p> <p>Independent Cancer Taskforce (2015) Achieving world-class cancer outcomes: a strategy for England 2015-2020</p>

References

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2. Cancer Research UK. [Symptoms](#). Accessed February 2022.
3. Cancer Research UK. [Stages of non-Hodgkin lymphoma](#). Accessed February 2022.
4. Public Health England. [Cancer registration statistics, England: final release, 2018](#). Accessed February 2022.
5. Cancer Research UK. [Survival](#). Accessed February 2022.
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.