

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Ibrutinib with R-CHOP for untreated mantle cell lymphoma when an autologous stem cell transplant is suitable

Final scope

Remit/evaluation objective

To appraise the clinical and cost effectiveness of ibrutinib with R-CHOP (rituximab with cyclophosphamide, doxorubicin, vincristine and prednisolone) within its marketing authorisation for untreated mantle cell lymphoma when an autologous stem cell transplant (ASCT) is suitable.

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 are around 590 new cases of mantle cell lymphoma diagnosed in the UK each year (comprising around 5% of all non-Hodgkin lymphoma cases).¹ Mantle cell lymphoma usually occurs in older adults and is more common in men than women at a ratio of 2.4:1.² Data from the UK between 2010 to 2019 indicates that the 5-year survival rate is 47%.³ Around 20-30% of people with untreated mantle cell lymphoma may be eligible for ASCT.⁴

NICE guideline 52 ([NG52](#)) recommends the following options for first-line treatment of mantle cell lymphoma:

- Chemotherapy in combination with rituximab for people with advanced stage mantle cell lymphoma who are symptomatic, taking into account the person's fitness when deciding on chemotherapy intensity.
 - Since NG52, bendamustine with rituximab is available for first-line use through an [NHS England commissioning policy](#) for treating mantle cell lymphoma. It is an option for less fit patients, as an alternative to other regimens such as rituximab with R-CHOP and rituximab, cyclophosphamide, vincristine and prednisolone (R-CVP).
 - NICE [technology appraisal guidance TA370](#) recommends bortezomib with rituximab, cyclophosphamide, doxorubicin and, prednisone (VR-CAP) as an option for previously untreated mantle cell lymphoma in adults for whom haematopoietic stem cell transplantation is unsuitable.
- Cytarabine-based immunochemotherapy for people with advanced-stage mantle cell lymphoma who are fit enough to have it.

Final scope for the evaluation of ibrutinib with R-CHOP for untreated mantle cell lymphoma when an autologous stem cell transplant is suitable

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- Radiotherapy for people with localised stage 1 or 2 mantle cell lymphoma.
- 'Watch and wait' for people with clinically non-progressive disease who are asymptomatic and when radiotherapy is not suitable.
- Consolidation with autologous stem cell transplantation when mantle cell lymphoma has had at least a partial response to induction chemotherapy in people who are fit enough for transplantation. Maintenance treatment with rituximab is recommended for some people with newly diagnosed mantle cell lymphoma, including those who are not fit enough for high-dose chemotherapy and where there has been a response to R-CHOP-based immunochemotherapy, or where there is remission after cytarabine-based induction and high-dose chemotherapy.

The British Society for Haematology Guideline for diagnosis and management of mantle cell lymphoma⁵ states that when ASCT is suitable, people should be offered an induction regimen containing rituximab and high-dose cytarabine. If there is a response to induction, consolidation with ASCT should be offered, followed by rituximab maintenance therapy.

The technology

Ibrutinib (Imbruvica, Johnson & Johnson Innovative Medicine) with R-CHOP has a marketing authorisation in the UK for treating adults with previously untreated mantle cell lymphoma who would be eligible for an autologous stem cell transplant. The marketing authorisation states that treatment with ibrutinib plus R-CHOP should be alternated with R-DHAP (rituximab, dexamethasone, cytarabine, and cisplatin) (or R-DHAox: rituximab, dexamethasone, cytarabine, and oxaliplatin) without ibrutinib, and followed by ibrutinib monotherapy (see the [Summary of Product Characteristics](#) for more detail).

Intervention	Ibrutinib with R-CHOP, alternating with R-DHAP or R-DHAox without ibrutinib, with or without ASCT, followed by ibrutinib monotherapy.
Population	Adults with untreated mantle cell lymphoma when an ASCT is suitable
Subgroups	If evidence allows, subgroups based on baseline clinical disease characteristics, cytology of mantle cell lymphoma, p53 expression and receipt of rituximab maintenance may be considered.

Comparators	<p>Established clinical management without ibrutinib for induction, consolidation and maintenance phases, including but not limited to:</p> <p>Induction phase:</p> <ul style="list-style-type: none"> • Alternating R-CHOP and R-DHAP or R-DHAOx • Acalabrutinib with bendamustine and rituximab (subject to NICE evaluation) <p>Consolidation phase:</p> <ul style="list-style-type: none"> • ASCT <p>Maintenance phase:</p> <ul style="list-style-type: none"> • Rituximab.
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • overall survival • failure-free 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	Related technology appraisals:

	<p>Bortezomib for previously untreated mantle cell lymphoma (2015) NICE technology appraisal guidance 370</p> <p>Related technology appraisals in development:</p> <p>Acalabrutinib with bendamustine and rituximab for untreated mantle cell lymphoma NICE technology appraisal guidance [ID6155] publication to be confirmed</p> <p>Related NICE guidelines:</p> <p>Non-Hodgkin's lymphoma: diagnosis and management (2016) NICE guidance NG52</p>
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References

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4. Martin P, Cohen JB et al. Treatment Outcomes and Roles of Transplantation and Maintenance Rituximab in Patients With Previously Untreated Mantle Cell Lymphoma: Results From Large Real-World Cohorts. *J Clin Oncol*. 2023 Jan 20;41(3):541-554. doi: 10.1200/JCO.21.02698.
5. Eyre TA, Bishton MJ et al. [Diagnosis and management of mantle cell lymphoma: A British Society for Haematology Guideline](#). *Br J Haematol*. 2024; 204(1): 108–126.