NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final draft guidance

Zanubrutinib for treating relapsed or refractory mantle cell lymphoma

1 Recommendations

1.1 Zanubrutinib can be used as an option to treat relapsed or refractory mantle cell lymphoma in adults who have had 1 line of treatment only. Zanubrutinib can only be used if the company provides it according to the commercial arrangement (see section 2).

1.2 Use the least expensive option of the suitable treatments (including zanubrutinib and ibrutinib), having discussed the advantages and disadvantages of the available treatments with the person with the condition. Take account of administration costs, dosages, price per dose and commercial arrangements.

1.3 This recommendation is not intended to affect treatment with zanubrutinib that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS healthcare professional consider it appropriate to stop.

What this means in practice

Zanubrutinib must be funded in the NHS in England to treat relapsed or refractory mantle cell lymphoma after 1 line of treatment in adults, if it is considered the

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most suitable treatment option. Zanubrutinib must be funded in England within 30 days of final publication of this guidance.

The least expensive option of the available treatments (including zanubrutinib and ibrutinib) that is suitable should be used. This should take into account administration costs, dosages, price per dose and commercial arrangements.

There is enough evidence to show that zanubrutinib provides benefits and value for money, so it can be used routinely across the NHS in this population.

Why the committee made these recommendations

Zanubrutinib is licensed for treating relapsed or refractory mantle cell lymphoma after at least 1 treatment. But for this evaluation, zanubrutinib was considered for treating relapsed or refractory mantle cell lymphoma after 1 line of treatment only.

Usual treatment for relapsed or refractory mantle cell lymphoma after 1 line of treatment is ibrutinib. Zanubrutinib works in a similar way to ibrutinib and would be offered to a similar population.

The clinical effectiveness evidence for zanubrutinib comes from 2 small studies in which zanubrutinib was not compared with any other treatments. These trials included people who had had 1 or more lines of treatment. Data from people who had had only 1 line of treatment, in line with the proposed positioning of Zanubrutinib, was preferred for this evaluation.

The results from an indirect treatment comparison are uncertain because of differences between the people in the included trials for zanubrutinib and ibrutinib. But the results suggest that zanubrutinib is likely to work at least as well as ibrutinib in this population.

Evidence from a database review of US clinical practice also supports that zanubrutinib is likely to work as well as ibrutinib for treating relapsed or refractory mantle cell lymphoma after 1 line of treatment only.

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There are uncertainties with the economic model, so the cost-effectiveness estimates are uncertain. But a cost comparison suggests that zanubrutinib has similar or lower costs to ibrutinib. So zanubrutinib can be used.

For all evidence, see the committee papers. For more information on NICE's evaluation of ibrutinib, see the committee discussion section in NICE's technology appraisal guidance on ibrutinib for treating relapsed or refractory mantle cell lymphoma.

2 Information about zanubrutinib

Marketing authorisation indication

2.1 Zanubrutinib (Brukinsa, BeiGene) is indicated for the 'treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy'

Dosage in the marketing authorisation

2.2 The dosage schedule is available in the summary of product characteristics for zanubrutinib.

Price

2.3 The list price for zanubrutinib is £4,928.65 for a 120 pack of 80-mg capsules (excluding VAT, BNF online, accessed May 2025).

2.4 The company has a commercial arrangement (simple discount patient access scheme). This makes zanubrutinib available to the NHS with a discount. The size of the discount is commercial in confidence.

Carbon Reduction Plan

2.5 For information, the Carbon Reduction Plan for UK carbon emissions is published on the company's webpage on responsible business and sustainability.

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3 Implementation

3.1 Section 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 90 days of its date of publication. Because zanubrutinib has been recommended through the cost-comparison process, NHS England and integrated care boards have agreed to provide funding to implement this guidance 30 days after publication.

3.2 Chapter 2 of Appraisal and funding of cancer drugs from July 2016 (including the new Cancer Drugs Fund) – A new deal for patients, taxpayers and industry states that for those drugs with a draft recommendation for routine commissioning, interim funding will be available (from the overall Cancer Drugs Fund budget) from the point of marketing authorisation, or from release of positive draft guidance, whichever is later. Interim funding will end 90 days after positive final guidance is published (or 30 days in the case of drugs with an Early Access to Medicines Scheme designation or cost comparison evaluation), at which point funding will switch to routine commissioning budgets. The NHS England Cancer Drugs Fund list provides up-to-date information on all cancer treatments recommended by NICE since 2016. This includes whether they have received a marketing authorisation and been launched in the UK.

3.3 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 60 days of the first publication of the final draft guidance.

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3.4 When NICE recommends a treatment ‘as an option’, the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has mantle cell lymphoma that is relapsed or refractory after 1 treatment and the healthcare professional responsible for their care thinks that zanubrutinib is the right treatment, it should be available for use, in line with NICE’s recommendations.

4 Evaluation committee members and NICE project team

Evaluation committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered as a streamlined evaluation by the lead team of committee C.

Committee members are asked to declare any interests in the technology being evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

Chair

Steve O’Brien

Chair, technology appraisal committee C

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

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