NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final draft guidance

Lisocabtagene maraleucel for treating relapsed or refractory large B-cell lymphoma after 2 or more lines of systemic treatment (review of TA987) [ID6619]

1 Recommendations

1.1 Lisocabtagene maraleucel can be used as an option for treating relapsed or refractory diffuse large B-cell lymphoma or primary mediastinal large B-cell lymphoma after 2 or more lines of systemic treatment in adults. Lisocabtagene maraleucel 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 lisocabtagene maraleucel and axicabtagene ciloleucel), 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 lisocabtagene maraleucel 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

Lisocabtagene maraleucel must be funded in the NHS in England for the condition and population in the recommendations, if it is considered the most

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

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

Why these recommendations were made

This evaluation is a review of NICE technology appraisal guidance TA987.

For this evaluation, the company asked for lisocabtagene maraleucel (liso-cel) to be considered only for relapsed or refractory diffuse large B-cell lymphoma or primary mediastinal large B-cell lymphoma after 2 or more lines of systemic treatment. This does not include everyone who it is licensed for.

Usual treatment at this point in the care pathway is axicabtagene ciloleucel (axi-cel) which is a chimeric antigen receptor (CAR) T-cell therapy. Liso-cel is also a CAR-T, so works in a similar way to axi-cel and would be offered to the same population.

Evidence from clinical practice in the US suggests people having liso-cel could have a similar amount of time before their lymphoma gets worse and may live for a similar amount of time as people having axi-cel.

Liso-cel has not been directly compared with axi-cel in a clinical trial. The results of an indirect comparison of 2 separate trials are uncertain because of differences between the trials, specifically:

- the use of other treatments given before CAR-T infusion
- the trial populations
- the number of people in the trials who had the infusions of liso-cel or axi-cel
- when the trials were done.

Results from the indirect comparison suggest liso-cel is associated with comparable outcomes to axi-cel. These results are considered confidential by the company but align with earlier published literature. The indirect comparison also suggests liso-cel is better tolerated than axi-cel. So, liso-cel could be an option for people who are older, frailer or less able to tolerate axi-cel.

To be recommended as a treatment option, liso-cel should be likely to provide similar outcomes, and cost less or have similar costs as axi-cel (see NICE's cost comparison methods). The results of cost-comparison analyses show the costs of liso-cel are similar to or less than axi-cel. Because of the uncertainties in the clinical evidence, more analyses were done to explore the impact of changing the assumptions about resource use and costs. These focused on intravenous immunoglobulin use and admission to intensive care units. In all analyses the costs of liso-cel are similar to or less than axi-cel. So, liso-cel can be used.

For all evidence see the committee papers. For more information on NICE's evaluation of axi-cel, see the committee discussion section in NICE's technology appraisal guidance on axi-cel for treating diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma after 2 or more systemic therapies.

2 Information about lisocabtagene maraleucel

Marketing authorisation indication

2.1 Lisocabtagene maraleucel (Breyanzi, Bristol Myers Squibb) is indicated for the 'treatment of adult patients with relapsed or refractory diffuse large B cell lymphoma, primary mediastinal large B-cell lymphoma and follicular lymphoma grade 3B, after two or more lines of systemic therapy'.

Dosage in the marketing authorisation

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

Price

2.3 The list price of lisocabtagene maraleucel is £297,000.00 for a single infusion of chimeric antigen receptor T cells (excluding VAT; company submission).

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

Sustainability

2.5 For information, the Carbon Reduction Plan for UK carbon emissions is published on Bristol Myers Squibb's webpage on sustainability..

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 lisocabtagene maraleucel 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 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.

3.3 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 relapsed or refractory diffuse large B cell lymphoma or primary mediastinal large B-cell lymphoma and the healthcare professional responsible for their care thinks that lisocabtagene maraleucel 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

This topic was considered as a cost comparison evaluation by the chair and vice chair 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.

James Fotheringham
Chair, technology appraisal committee C

Richard Nicholas
Vice 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 or principal technical adviser.

Madiha Adam
Technical lead

Claire Hawksworth and Emily Leckenby

Technical advisers

Leena Issa

Project manager

Lorna Dunning

Associate director

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