NICE National Institute for Health and Care Excellence

NICE guidance

Ublituximab for treating relapsing multiple sclerosis

Technology appraisal guidance
Published: 18 December 2024

www.nice.org.uk/guidance/ta1025

Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

1.1 Ublituximab is recommended as an option for treating relapsing forms of multiple sclerosis, defined as active by clinical or imaging features in adults, only if:

- the multiple sclerosis is relapsing–remitting, and
- the company provides it according to the commercial arrangement.

1.2 Use the least expensive option of the available treatments (including ublituximab, ocrelizumab and ofatumumab). Take account of administration costs, dosages, price per dose and commercial arrangements. If the least expensive option is unsuitable, people with the condition and their healthcare professional should discuss the advantages and disadvantages of other treatments.

1.3 This recommendation is not intended to affect treatment with ublituximab 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.

Why these recommendations were made

Treatment options for active relapsing–remitting multiple sclerosis include immunomodulatory treatments such as teriflunomide and anti-CD20 monoclonal antibodies such as ocrelizumab and ofatumumab. Ublituximab is another treatment option that works in a similar way to ocrelizumab and ofatumumab and would be offered to the same population.

Clinical trial evidence shows that ublituximab is more effective at reducing the number of relapses than teriflunomide. Ublituximab has not been directly compared in a clinical trial with ocrelizumab and ofatumumab. But the results of an indirect comparison suggest that it is likely to work as well as these.

A comparison of ublituximab with ocrelizumab and ofatumumab using NICE's cost comparison methods suggests ublituximab has similar benefits to and lower costs than ocrelizumab and ofatumumab. So, ublituximab is recommended.

For all evidence see the committee papers. For more information of NICE's evaluation of ocrelizumab and ofatumumab, see the committee discussion sections in NICE's technology appraisal guidance on ocrelizumab for treating relapsing–remitting multiple sclerosis and ofatumumab for treating relapsing multiple sclerosis.

2 Information about ublituximab

Marketing authorisation indication

2.1 Ublituximab (Briumvi, Neuraxpharm) is indicated for 'the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features'.

Dosage in the marketing authorisation

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

Price

2.3 The list price of ublituximab is £2,947.00 per 150-mg vial (excluding VAT, company submission, accessed November 2024).

2.4 The company has a commercial arrangement. This makes ublituximab available to the NHS with a discount. The size of the discount is commercial in confidence.

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 3 months of its date of publication. Because ublituximab 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 Section 4f of The Innovative Medicines Fund Principles states that a discretionary source of early funding (from the overall Innovative Medicines Fund budget) is available for certain medicines recommended by NICE. In this instance, interim funding has been agreed for ublituximab. 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.

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 2 months of the first publication of the final draft guidance.

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 active relapsing–remitting multiple sclerosis and the healthcare professional responsible for their care thinks that ublituximab 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 highly specialised technologies evaluation committee is a standing advisory committee of NICE. This topic was considered by the lead team of the committee, which includes the chair and vice chair.

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 and vice chair

Paul Arundel and Iolo Doull
Chair and vice chair, highly specialised technologies evaluation committee

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.

Sally Lewis
Technical lead

Adam Brooke
Technical adviser

Jeremy Powell
Project manager

Emily Crowe

Associate director

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