NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final draft guidance

Crovalimab for treating paroxysmal nocturnal haemoglobinuria in people 12 years and over

1 Recommendations

1.1 Crovalimab is recommended, within its marketing authorisation, as an option for treating paroxysmal nocturnal haemoglobinuria in people 12 years and over who weigh of 40 kg or more. Crovalimab is only recommended if the company provides it according to the commercial arrangement (see section 2).

1.2 If people with the condition and their healthcare professional consider crovalimab to be 1 of a range of suitable treatments, after discussing the advantages and disadvantages of all the options, the least expensive should be used. Administration costs, dosages, price per dose and commercial arrangements should all be taken into account.

Why these recommendations were made

Usual treatment for paroxysmal nocturnal haemoglobinuria is eculizumab or ravulizumab. Eculizumab biosimilars are also available, but very few people have them in clinical practice, so they have not been included as comparators. Crovalimab works in a similar way to eculizumab and ravulizumab, and would be offered to the same population.

Clinical trial evidence shows that crovalimab works as well as eculizumab. Crovalimab has not been directly compared with ravulizumab in a clinical trial, but indirect comparisons suggest that it is likely to be as effective.

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When switching from eculizumab or ravulizumab to crovalimab, some people can experience adverse events called transient immune complex reactions. But, these events usually do not last long and so are not included in the economic model.

A cost comparison suggests crovalimab has lower costs than eculizumab or ravulizumab. So crovalimab is recommended.

For all evidence see the committee papers. For more information on NICE's evaluation of ravulizumab, see the committee discussion section in NICE's technology appraisal guidance on ravulizumab for treating paroxysmal nocturnal haemoglobinuria.

2 Information about crovalimab

Marketing authorisation indication

2.1 Crovalimab (Piasky, Roche) is indicated for the 'treatment of adult and paediatric patients 12 years of age or older with a weight of 40 kg and above with paroxysmal nocturnal haemoglobinuria'.

Dosage in the marketing authorisation

2.2 The dosage schedule will be available in the summary of product characteristics for crovalimab.

Price

2.3 The list price for crovalimab is £9,500 per 340-mg vial (excluding VAT; company submission accessed September 2024).

2.4 The company has a commercial arrangement (simple discount patient access scheme). This makes crovalimab 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 crovalimab 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 2 months 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 paroxysmal nocturnal haemoglobinuria and the healthcare professional responsible for their care thinks that crovalimab 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 by the lead team of the highly specialised technologies evaluation committee, which includes chair Dr Paul Arundel and vice-chair Professor Iolo Doull.

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

Paul Arundel

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.

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