NICE National Institute for Health and Care Excellence

NICE guidance

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

Technology appraisal guidance
Published: 20 November 2024

www.nice.org.uk/guidance/ta1019

# 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 Crovalimab is recommended, within its marketing authorisation, as an option for treating paroxysmal nocturnal haemoglobinuria in people 12 years and over who weigh 40 kg or more. It is recommended for people who:

- have haemolysis with clinical symptoms indicating high disease activity
- are clinically stable after having a complement component 5 inhibitor for at least the past 6 months.

Crovalimab is only recommended if the company provides it according to the commercial arrangement.

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.

When switching from eculizumab or ravulizumab to crovalimab, some people can experience adverse events called type 3 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:

- in patients with haemolysis with clinical symptom(s) indicative of high disease activity.
- in patients who are clinically stable after having been treated with a complement component 5 (C5) inhibitor for at least the past 6 months.'

## Dosage in the marketing authorisation

2.2 The dosage schedule is 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. 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.

**George Millington**
Technical lead

**Lizzie Walker**
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**Louise Jafferally**
Project manager

**Ross Dent**

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ISBN: 978-1-4731-6311-9