NICE National Institute for Health and Care Excellence

NICE guidance

Faricimab for treating wet age-related macular degeneration

Technology appraisal guidance
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www.nice.org.uk/guidance/ta800

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 Faricimab is recommended as an option for treating wet age-related macular degeneration in adults, only if:

- the eye has a best-corrected visual acuity between 6/12 and 6/96
- there is no permanent structural damage to the central fovea
- the lesion size is 12 disc areas or less in greatest linear dimension
- there are signs of recent disease progression (for example, blood vessel growth as shown by fluorescein angiography, or recent visual acuity changes)
- the company provides faricimab according to the commercial arrangement.

1.2 If patients and their clinicians consider faricimab to be 1 of a range of suitable treatments (including aflibercept and ranibizumab), choose the least expensive treatment. Take account of administration costs, dosage, price per dose and commercial arrangements.

1.3 Only continue faricimab if an adequate response to treatment is maintained. Criteria for stopping should include persistent deterioration in visual acuity and anatomical changes in the retina.

1.4 These recommendations are not intended to affect treatment with faricimab that was started in the NHS before this guidance was published. People having treatment outside these recommendations may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

Why the committee made these recommendations

Wet age-related macular degeneration is usually treated with aflibercept or ranibizumab, which are already recommended by NICE for treating wet age-related macular degeneration. Faricimab is another treatment option that works in a similar way.

Evidence from clinical trials shows that faricimab is as effective as aflibercept. An indirect comparison of faricimab with ranibizumab also suggests similar clinical effectiveness.

A cost comparison suggests faricimab has similar costs and overall health benefits to aflibercept or ranibizumab. So, faricimab is recommended for treating wet age-related macular degeneration if it is used in the same population as aflibercept and ranibizumab.

2 Information about faricimab

Marketing authorisation indication

2.1 Faricimab (Vabysmo, Roche) is indicated for 'the treatment of adults with neovascular (wet) age-related macular degeneration'.

Dosage in the marketing authorisation

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

Price

2.3 Faricimab costs £857 for 1 vial of 120 mg per 1 ml solution for injection (excluding VAT; company submission, accessed April 2022).

2.4 The company has a commercial arrangement. This makes faricimab available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

3 Committee discussion

The appraisal committee considered evidence submitted by Roche, a review of this submission by the evidence review group (ERG), and responses from stakeholders. See the committee papers for full details of the evidence.

Comparators

Aflibercept and ranibizumab are appropriate comparators

3.1 Aflibercept and ranibizumab are anti-vascular endothelial growth factor (anti-VEGF) injections recommended by NICE for treating wet age-related macular degeneration. Faricimab is another anti-VEGF injection that works in a similar way to aflibercept and ranibizumab, but it also targets the Ang-2 pathway. The company proposes that faricimab will extend the time needed between injections compared with aflibercept and ranibizumab. The ERG suggested aflibercept was the most appropriate comparator for faricimab. Clinical experts said that the 2 treatments are both used. But they said aflibercept may be used more than ranibizumab. The ERG's clinical experts suggested that 65% of people have aflibercept. The committee concluded that aflibercept and ranibizumab were both appropriate NICE-recommended comparators.

Clinical evidence

Evidence from 2 clinical trials, TENAYA and LUCERNE, shows similar clinical effectiveness of faricimab and aflibercept

3.2 Clinical evidence for faricimab compared with aflibercept came from 2 clinical trials. These were TENAYA and LUCERNE. Both were phase 3 randomised controlled trials that compared faricimab with aflibercept in 1,329 adults. After the initial loading doses specified in the summary of product characteristics, aflibercept was given every 8 weeks and faricimab was administered every 8, 12 or 16 weeks based on an

assessment of disease activity at weeks 20 and 24. The assessment was based on objective prespecified criteria (best corrected visual acuity and optical coherence tomography) and physician's clinical assessment. People stayed on the fixed dosing intervals until week 60 without having any other treatment. The primary outcome measure was the mean change in best corrected visual acuity from baseline averaged over 40, 44 and 48 weeks. The difference in adjusted mean best corrected visual acuity from baseline at weeks 40, 44 and 48 was 0.4 letters, 95% confidence interval -0.9 to 1.6. The results were also reported averaged over 52, 56 and 60 weeks (these are considered confidential by the company and cannot be reported here). The evidence suggested that both treatments were similarly effective and had similar adverse events. Because there is only data up to 112 weeks, there is some uncertainty about how many faricimab injections are needed beyond the first 2 years. Despite the uncertainty, the committee considered that faricimab is likely to be similarly clinically effective as aflibercept.

Faricimab is likely to have similar clinical effectiveness as ranibizumab

3.3 The company did a network meta-analysis comparing faricimab with ranibizumab and aflibercept. The ERG considered that the network meta-analysis showed that faricimab has similar clinical effectiveness and had similar adverse events to aflibercept and ranibizumab. Also, clinical opinion suggests that the treatments are similar. The committee concluded that there was sufficient evidence of similar clinical efficacy for faricimab compared with ranibizumab.

Cost comparison

Faricimab is likely to be cost saving or have similar costs compared with aflibercept or ranibizumab

3.4 The company base case assumed there would be fewer injections and monitoring visits needed for faricimab compared with the comparators. But the committee was aware that in NHS clinical practice faricimab may have a similar dosing regimen as aflibercept and ranibizumab. This is to

reduce inconsistencies in clinical practice and chance of error in busy clinical settings. Because of this, along with the lack of long-term data, the committee considered scenarios in which the number of injections and monitoring visits was the same for faricimab, aflibercept and ranibizumab after the initial loading doses. The committee acknowledged that if the time needed between injections is lengthened, then the cost of faricimab would reduce. When taking account of the commercial arrangements for all treatments, the committee was satisfied that the total cost associated with faricimab was similar or lower than aflibercept or ranibizumab (the exact results are confidential and cannot be reported here). The committee therefore recommended faricimab for treating wet age-related macular degeneration in line with the previous recommendations for aflibercept and ranibizumab.

Other factors

There are no equality issues relevant to the recommendations

3.5 The committee did not identify any equality issues.

4 Implementation

4.1 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 clinical commissioning groups, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication. Because faricimab has been recommended through the fast track appraisal process, NHS England and commissioning groups have agreed to provide funding to implement this guidance 30 days after publication.

4.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal 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 appraisal document.

4.3 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 wet age-related macular degeneration and the doctor responsible for their care thinks that faricimab is the right treatment, it should be available for use, in line with NICE's recommendations.

5 Appraisal committee members and NICE project team

Appraisal committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by committee C.

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

The minutes of each appraisal committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

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

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Accreditation