NICE National Institute for Health and Care Excellence

NICE guidance

Vanzacaftor-tezacaftor-deutivacaftor for treating cystic fibrosis with 1 or more F508del mutations in the CFTR gene in people 6 years and over

Technology appraisal guidance
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www.nice.org.uk/guidance/ta1085

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 Vanzacaftor-tezacaftor-deutivacaftor (Vnz-Tez-Diva) can be used as an option to treat cystic fibrosis in people 6 years and over who have at least 1 F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. Vnz-Tez-Diva can only be used if the company provides it according to the commercial arrangement.

1.2 Use the least expensive option of the suitable treatments (including Vnz-Tez-Diva and ivacaftor-tezacaftor-elexacaftor [Iva-Tez-Elx]), 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 Vnz-Tez-Diva 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. For children or young people, this decision should be made jointly by the healthcare professional, the child or young person, and their parents or carers.

What this means in practice

Vnz-Tez-Diva 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. Vnz-Tez-Diva must be funded in England within 30 days of final publication of this guidance.

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

NICE has produced tools and resources to support the implementation of this guidance.

Why these recommendations were made

Usual treatment for cystic fibrosis with at least 1 F508del mutation in the CFTR gene is Iva-Tez-Elx, which is licensed for people 2 years and over. Vnz-Tez-Diva works in a similar way and is licensed for people 6 years and over.

Clinical trial evidence shows that Vnz-Tez-Diva is as effective as Iva-Tez-Elx in people 12 years and over at improving lung function, growth and weight gain and reducing the number of lung infections. It has not been directly compared with Iva-Tez-Elx in people aged 6 to 11 years but is likely to work as well in these people.

A cost comparison of Vnz-Tez-Diva and Iva-Tez-Elx in people 6 years and over suggests that the costs are similar. But Iva-Tez-Elx is licensed for people with at least 1 F508del mutation and no other responsive mutation. So, Vnz-Tez-Diva can only be used in people 6 years and over who have at least 1 F508del mutation in the CFTR gene.

For all evidence see the committee papers. For more information on NICE's evaluation of Iva–Tez–Elx, see the committee discussion section in NICE's technology appraisal guidance on ivacaftor–tezacaftor–elexacaftor, tezacaftor–ivacaftor and lumacaftor–ivacaftor for treating cystic fibrosis.

2 Information about vanzacaftor-tezacaftor-deutivacaftor

Marketing authorisation indication

2.1 Vanzacaftor-tezacaftor-deutivacaftor (Vnz-Tez-Diva; Alyftrek, Vertex) is indicated for 'the treatment of cystic fibrosis (CF) in people aged 6 years and older who have at least one F508del mutation or another responsive mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene'.

Dosage in the marketing authorisation

2.2 The dosage schedule for Vnz-Tez-Diva is available in the summary of product characteristics for:

- Vnz 10 mg, Tez 50 mg and Diva 125 mg tablets
- Vnz 4 mg, Tez 20 mg and Diva 50 mg tablets.

Price

2.3 The list price for Vnz-Tez-Diva (excluding VAT; company submission) is £16,110.00 per:

- 84-tablet pack of Vnz 10 mg, Tez 50 mg and Diva 125 mg
- 56-tablet pack of Vnz 4 mg, Tez 20 mg and Diva 50 mg.

2.4 The company has a commercial arrangement with NHS England. As part of this agreement, Vnz-Tez-Diva is available to the NHS with a discount. The size of the discount is commercial in confidence.

Carbon Reduction Plan

2.5 For information, Vertex did not disclose its Carbon Reduction Plan for UK carbon emissions.

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 vanzacaftor-tezacaftor-deutivacaftor (Vnz-Tez-Diva) 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. NHS England has agreed a confidential commercial agreement that enables access to Vnz-Tez-Diva from the date of the final draft guidance.

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 cystic fibrosis with at least 1 F508del mutation in the CFTR gene and the healthcare professional responsible for their care thinks that Vnz-Tez-Diva 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 (HST) committee is a standing advisory committee of NICE. This topic was considered as a cost comparison evaluation by the lead team of the HST committee, which includes the chair and the 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

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.

Bethany Crompton
Technical lead

Caron Jones
Technical adviser

Leena Issa
Project manager

Lorna Dunning

Associate director

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